No. 83-1998

In the Supreme Court

OF THE

United States

OCTOBER TERM, 1983

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E.R. SQUIBB & SONS, INC.,
Petitioner,
vs.
THERESE MARIE COLLINS, NOW KNOWN as THERESE MARIE GASTROW; ELI LILLY COMPANY: REXALL DRUG COMPANY; ABBOTT LABORATORIES; BOYLE AND COMPANY; COOPER LABORATORIES, INC. (formerly Brewer and Company, Inc. and Sherman Laboratories); VALE CHEMICAL COMPANY, INC.; UPJOHN COMPANY; COLE PHARMACAL COMPANY: MCNEIL LABORATORIES, INC.; CARNRICK LABORATORIES, a Division of G. W. Carnrick Company; EMONS INDUSTRIES, INC. (formerly AmfreGrant and Grant Chemical Company); E. S. MILLER LABORATORIES, A Division of Smith, Miller & Patch Products; PREMO PHARMACEUTICAL LABORATORIES, INC.; KREMERS-URBAN COMPANY; MERCK, SHARP & DOHME; and WILLIAM A. WEBSTER COMPANY; AND OTHERS,
Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE SUPREME COURT OF WISCONSIN

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71 pp

QUESTIONS PRESENTED

1. Whether a state violates the Due Process and Equal Protections Clauses of the 14th Amendment by the creation of a rule under which any single member of an industry involved in the manufacture of a tangible product can be compelled by the arbritrary decision of a plaintiff to defend in the Courts of the state and be subjected to potential liability for damages solely on the basis of being a manufacturer of the product and not because of any rational connection between the conduct of the industry member and the injuries of the plaintiff.

2. Whether manufacturers of a particular pharmaceutical product are denied equal protection under the law when a special rule of law is established which is applicable to them only and not applicable to other manufacturers involved in cases of the same character.

3. Whether due process and equal protection are violated by a state Court action which precludes a class of defendants from the right to a fair and meaningful hearing on the question of whether any of the defendants manufactured the alleged injury causing product.

4. Whether the commerce or supremacy clauses are violated by state action which frustrates, impedes and erodes federal policies encouraging the manufacturing and distribution of generic drugs.

5. Whether the Wisconsin Supreme Court has unconstitutionally applied Article I, Section 9 of the Wisconsin Constitution in violation of the said United States Constitution provisions by creating a new tort rule in derogation of Petitioner's (and/or other members of its industry) rights?

LIST OF PARTIES

All of the parties appearing in the litigation at the Wisconsin State Supreme Court level are identified in the caption of this Petition. Therese M. Collins, now known as Therese Marie Gastrow, is the Plaintiff at the trial court level while all remaining parties are pharmaceutical manufacturers and/or marketers named as defendants in the Milwaukee County Circuit Court Wisconsin lawsuit.

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To the Honorable Warren E. Burger, Chief Justice of the United States Supreme Court, and to the Honorable Associate Justices of the United States Supreme Court:

Petitioner, E.R. Squibb & Sons, Inc., respectfully requests this Court to issue a Writ of Certiorari to review the judgment and the opinion of the Wisconsin State Supreme Court entered in this proceeding on January 4, 1984.

OPINIONS BELOW

The opinion of the Wisconsin State Supreme Court is reported in 116 Wis. 2d 166, ... N.W. 2d ..... (1984) on bypass from the Wisconsin Court of Appeals and is reprinted in Appendix A, p. A-1 to this Petition.

As noted, the Wisconsin State Supreme Court granted direct review of the Milwaukee County Circuit Court decision, pursuant to Rules 808.05 and 809.60, Wis. Stats.

JURISDICTION

The judgment and decision of the Wisconsin State Supreme Court sought to be reviewed was dated January 4, 1984. A timely motion for reconsideration was duly filed on January 24, 1984. (Appendix B). The motion for reconsideration was denied by the Wisconsin Supreme Court on February 27, 1984. (Appendix C). The jurisdiction of this Honorable Court is invoked pursuant to Title 28, U.S.C.A. Sec. 1257(3).

CONSTITUTIONAL PROVISIONS INVOLVED

This case involves Article I, Section 9 of the Wisconsin Constitution. It may be found in the official Wisconsin Statutes and West's Wisconsin Statutes Annotated, Volume 1, to-wit:

> "9. Remedy for injuries or wrongs
> "Section 9. Every person is entitled to a certain remedy in the laws for all injuries, or wrongs which he may receive in his person, property, or character; he ought to obtain justice freely, and without being obliged to purchase it, completely and without denial, promptly and without delay, comformably to the laws."

This case also involves the 14th Amendment clause to the United States Constitution and Article I, Section 8, Commerce Clause which respectively provide:

> " 'All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of

the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; *nor shall any State deprive any person of life, liberty or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.*' (emphasis added)"

"To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."

STATEMENT OF THE CASE

The Wisconsin Supreme Court has devised a new theory of recovery for civil damages, the national consequence of which can only best be described as disastrous for product manufacturers. In so doing, they not only create a chilling effect on a major industry whose place in our society is one of unquestioned need, but, at the same time, have managed to violate, in several critical aspects, the constitutional rights and guarantees of Petitioner, the pharmaceutical industry and potentially all manufacturers of products across this land.

Under this newly created remedy, innocent pharmaceutical manufacturers will be held answerable to the Plaintiff here and to thousands of other "DES plaintiffs" without the need to establish a nexus between the manufacturer's conduct, or its product, and the injury claimed.

Although the decision is framed in the context of "DES cases", the pronouncement is made that the remedy will apply in cases that are "factually similar." With this precedent, no industry or category of products is left free from a threat of presumed liability. By analogy, an allegation of harm founded on a statistical link with consumption of oleomargarine imperils every manufacturer of that product, without regard to their domicile or marketing area.

A. History of DES

Diethylstilbestrol, commonly known as Stilbestrol or DES, is a synthetic estrogen which has been proven to have physiologic properties identical to the natural estrogens, estradiol and estrone. Estrogens are the female hormones which are responsible for secondary sex characteristics and are essential to healthy and successful pregnancies.

Prior to the creation of DES, natural estrogens were extracted from natural sources such as mare's urine. This procedure was tremendously expensive, cumbersome, and thus the medication was not readily available to all that needed it. Nevertheless, since the 1930's, estrogen replacement therapy was recognized as an important treatment of various hormonal problems in women. In the 1930's experiments begun by scientists attempted to develop synthetic substitutes for the natural estrogens. The much needed DES was developed by British scientists operating under a grant from their government. It was first reported in the literature in 1938 by E.C. Dodds, L. Golberg and others (*Nature*, 41:247-248, 1938). The structure and configuration of DES was thus established in the late 1930's and experimentation revealed that DES mimicked the pharmacological effects of the natural estrogens, and as such, began to be used as a therapy for women who had hormone deficiencies.

During the late 1930's and early 1940's, and pursuant to the then applicable Federal Acts, several pharmaceutical companies submitted new drug applications (hereinafter "NDA's") to the Food and Drug Administration for the purpose of receiving approval for marketing DES. Since DES had been developed under a government grant, no one person held a patent for the chemical structure of the product and hence it could be manufactured by anyone wishing to do so. The original NDA's of these drug companies, including that of E.R. Squibb & Sons, Inc. (hereinafter

"Squibb"), sought to obtain approval for marketing DES for the treatment of senile vaginitis, menopausal symptoms, suppression of lactation and gonorrheal vaginitis in prepubertal girls. The various NDA's, including Squibb's, were approved during the latter part of 1941 pursuant to the then applicable Federal Food, Drug and Cosmetic Act, Pub.L.No. 717, 52 Stats. 1040, Sec. 201 (p) 1938. (App. p. 178)

Thereafter, the clinical study of DES was conducted by independent physicians at major medical centers. There was increasing interest, notably at Harvard and at the Joslin Clinic in Boston, in its use to save babies by treating problems of pregnancy. Through this research, it was discovered that hormonal deficiencies in pregnancy led to early miscarriage and that estrogen treatment could correct these deficiencies. Initially, scientists had used the expensive natural estrogens; however, when DES became available, they found that it had the same physiological effect and hence its safe and effective use was established.

By 1947, reports by several independent physicians appeared in the medical literature documenting the successful use of this medication. In response to these reports, and after obtaining input from clinical investigators several manufacturers filed separate and independent NDA's seeking permission to market DES in dosage size for use by the medical profession as an aid in certain problems of pregnancy. In 1947, Squibb and others submitted a supplemental NDA and obtained FDA approval to market 25 mg. tablets of DES for the control of certain endocrine disturbances of pregnancy. Subsequent to 1952, DES was declared by the FDA to be "generally recognized . . . as safe" and as such, the medication was no longer considered a "new drug." From this point forward, DES could be manufactured and sold by any company without filing an NDA. This action, on the part of the FDA, allowed any

company adhering to approved manufacturing practices to market DES for any previously approved use without filing an NDA. Ultimately, 200 to 300 companies marketed DES, at different times, in different forms, at different prices, with different labeling and for different indications.

The drug was used in pregnancy until 1971 when Dr. Arthur Herbst first published a paper in the New England Journal of Medicine, Volume 284, p. 278, April 22, 1971, reporting a statistical association between the use of DES during pregnancy and the appearance of clear cell adenocarcinoma of the vagina in a few offspring of women having ingested the drug. This form of cancer also appears in women not exposed to DES.[1] Not until 1971, after 30 years of clinical use, was there any report in the medical literature describing or reporting any adverse effect to the offspring of women having ingested the medication. It should be noted that several scientists reported in the literature during the 1940's and 1950's that the babies exposed to DES were absolutely healthy and normal in all respects.

At all relevant times, Squibb marketed DES only to be sold as a prescription medication to be used in pregnancy if the patient was threatening to abort or had a history of repeated miscarriages for the control of certain endocrine based dysfunctions. Squibb, throughout the 1950's and 1960's marketed its DES under its own trade name, Stilbetin. Furthermore, Squibb's DES during the relevant period of time was pink and did not match the description given by the Plaintiff's mother here. ("A little white uncoated pill smaller than an aspirin.")

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[1]The allegations by plaintiff as to medical causation, which are expressly denied by petitioner, have not been established by scientific evidence.

B. The Wisconsin Supreme Court's Rule

As of the time that the Wisconsin Supreme Court rendered its decision in January of 1984, an estimated 1,000 DES lawsuits were pending throughout the country. (App. A p. 181) The Wisconsin Supreme Court made it quite clear that it was "not dealing with an isolated unique set of circumstances which will never occur again . . ." Thereby, the Court felt justified in divining a completely novel remedy which substantially deviates from traditional legal principles and violates Petitioner's constitutional rights. In so doing, said Court created for the Plaintiffs a "new method of recovery", the consequences of which holds innocent defendants in a lawsuit in order to prevent the manufacturer having made the specific DES ingested from escaping liability. (App. A p. 181) In its ruling, the Wisconsin Supreme Court obviously recognizing its breach of constitutionally protected rights acknowledged that innocent defendants would be trapped in the new web of tort liability (App. A p. 198)

It is clear from the opinion that the Court fashioned this new remedy in order to assist the Plaintiff with the purported "insurmountable obstacle" of identifying the manufacturer of the DES ingested.

In creating this new rule, the Wisconsin Supreme Court looked to Article I, Section 9 of the Wisconsin Constitution as its primary authority for imposing liability on the pharmaceutical companies retroactively for acts which occurred four decades ago. Prior to the creation of this new rule, fairness principles required "that a plaintiff prove not only duty, breach of duty, and injury, but also legal causation between a defendant's conduct and a plaintiff's injury . . ." (App. A pp. 180-182) In contradiction to these long accepted principles, the Wisconsin Court allows the plaintiff to proceed with the case by merely proving that the arbitrarily chosen defendant sued by the plaintiff had

produced a "type of DES taken by plaintiff's mother." The obvious effect of the Court's decision is to eliminate the causation requirement and to implement a new test that allows the Plaintiff to select any manufacturer or manufacturers arbitrarily without requiring Plaintiff to establish a nexus between the injury and the scapegoat manufacturer's conduct or product.

C. Procedural History

The underlying lawsuit was commenced by the Plaintiff in the Milwaukee County Circuit Court in January of 1977. The complaint named 12 drug companies who allegedly produced and marketed DES. In February, 1978, the Plaintiff filed a second amended complaint naming five additional drug companies as defendants. (App. A p. 175) In May, 1981, the Defendants jointly and severally moved for summary judgment alleging that under the existing laws, the Plaintiff was not entitled to proceed with the lawsuit without identifying the specific manufacturer of the product allegedly ingested by Plaintiff's mother. (App. A pp. 177-178) In April, 1982 Circuit Judge Marvin C. Holz granted Defendants' motions for summary judgment.

In May of 1982, the Plaintiff moved the trial court requesting permission to ". . . amend her second amended complaint to name Eli Lilly as the sole defendant on the grounds that there was a reasonable probability that it manufactured the DES taken by plaintiff's mother. . ." (App. A p. 176) The trial court denied the Plaintiff's motion and later on September 16, 1982, entered judgment dismissing the Plaintiff's second amended complaint. (App. A p. 176)

The Plaintiff Collins appealed from that judgment. A bypass petition over the Wisconsin Court of Appeals was granted, thereby allowing the Wisconsin Supreme Court to hear the case directly. (App. A p. 173 and pp. 176-177)

On January 4, 1984, the Wisconsin Supreme Court rendered its decision which is sought to be reviewed by this petition. On January 24, 1984, a timely motion for reconsideration was filed with the Wisconsin Supreme Court by Petitioner and other defendants. (App. B). On February 27, 1984, the Wisconsin Supreme Court entered its order denying said motion. (App. C).

D. Federal Issues Presented to the Wisconsin Supreme Court

Plaintiff's brief to the Wisconsin Supreme Court requested the adoption of new tort principles such as those espoused by the California Supreme Court in *Sindell v. Abbott Laboratories,* 26 Cal.3d 588, 163 Cal. Rptr. 132, 607 P.2d 924 (1980); cert. denied 449 U.S. 912 (1980). Petitioner and other defendants urged the Court below that adoption of any such theories, under the circumstances present herein, would result in serious violation of Defendant's constitutional rights under the substantive and procedural due process clause, the equal protection clause of the 14th Amendment, and the commerce clause of the United States Constitution. Furthermore, the Defendants urged that any rule adopted by the Wisconsin Supreme Court would frustrate the enforcement of federal laws governing prescription drugs and would hence be in violation of the pre-emption doctrine. Surprisingly enough, the Wisconsin Supreme Court agreed that the necessary fundamental and inherent equities were not present in the California *Sindell* rule and rejected the same. Likewise, the Wisconsin Court rejected the other theories advanced by the Plaintiff which had been adopted by its sister state courts of New York, Michigan, and South Dakota.

The Wisconsin Court also rejected its own legal principles and furthermore, refused to follow the federal and state courts of Florida, Massachusetts, New Jersey and Texas which had previously rejected the novel liability

theories espoused by the Plaintiff. In adopting this new doctrine, the Wisconsin Supreme Court ignored and did not comment upon the constitutional claims raised by the Defendants.

E. Finality of Judgment

The judgment sought to be reviewed is final within the meaning of Title 28 U.S.C.A. § 1257, despite the fact that on the remand contemplated by the decision below, Petitioner may conceivably win ultimate vindication on grounds other than those set forth in this petition. The state judgment is final because it denied Petitioner its constitutional right to be free from the need to defend at all in the Wisconsin Courts.

The problem of what constitutes a final judgment under Section 1257 has occasioned difficulty over the years. See *Cox Broadcasting Corp. v. Cohn,* 420 U.S. 469, 476-87 (1975). But the Court has left no doubt whatever that a state judgment is final within the meaning of Section 1257 if it is in contravention of a federal claim to be free from the need to defend in a state court, notwithstanding the possibility that the defendant might ultimately prevail in proceedings on the merits in such court. Clear holdings to this effect include *Shaffer v. Heitner,* 433 U.S. 186, 195 n.12 (1977); *American Motorists Insurance Co. v. Starnes,* 425 U.S. 637, 642 n.3 (1976); *Michigan Central RR v. Mix,* 278 U.S. 492 (1929); *Harris v. Washington,* 404 U.S. 55, 56 (1971); *Local 438 Construction & General Laborers' Union AFL-CIO v. Curry,* 371 U.S. 542 (1963); and *Mercantile National Bank v. Langeau,* 371 U.S. 555, 557-58 (1963).

REASONS FOR ALLOWANCE OF THE WRIT

Fundamental constitutional protections under procedural due process and equal protection of the law overlap each other because of their fluid nature. Once the deprivation occurs on a constitutional level, it often contaminates a number of constitutional protections. Wisconsin's new Collins rule causes such a foul. It places the Petitioner and

the pharmaceutical community *across the country* in a gauntlet of liability. The Collins rule is not a local rule, but rather an "extraterritorial rule" that has nation-wide impact. The classes directly affected nation-wide are not just the pharmaceutical industry, but also the scientific community and insurance industry. Scientists were the *researchers and originators of DES and acted independently of the pharmaceutical industry.* The pharmaceutical industry depends upon the scientific community *for guidance in the safety and effectiveness of any drug.* Prior to 1971, the overwhelming weight of scientific opinion gave credence to the medical use of DES as an aid to women with hormonal problems *and to advance the state of health* for all.

The courts in *Morton v. Abbott Laboratories,* 538 F. Supp. 593 (M.D. Fla 1982), *Ryan v. Eli Lilly & Co.,* 514 F.Supp. 1004 (D. S.C. 1981), *Lyons v. Premo Pharmaceutical Labs. Inc.,* 170 N.J. Super. 183, 406 A.2d 185 (1979), and *Gray v. United States,* 445 F.Supp. 337 (S.D. Tex. 1978) all refused to change the fundamental concepts of causation under tort law in view of the inequities inherent in any of the new theories advanced therein. The Collins rule and other new theories of recovery cannot be harmonized in their reasoning, or as to their effect. Divergent views on the problem are illustrated by the discussion in *Collins* which considers and rejects (1) the alternative liability theory, (2) the concerted action theory, (3) the enterprise liability theory, (4) the market share theory, and (5) the civil conspiracy theory.

States of California, South Dakota, Michigan,[2] New York and Wisconsin all have created their own separate and

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[2]Almost simultaneously with the Wisconsin decision on which this petition is founded, the Michigan Supreme Court in *Abel v. Eli Lilly & Co.,* .... Mich. ...., 343 N.W. 2d 164 (1984), adopted its version of the alternative liability theory. Wisconsin counsel herein is advised that Michigan's counsel in the *Abel* case is also in the process of preparing a petition for Writ of Certiorari to this

distinct new rules of liability that place the Petitioner and the pharmaceutical industry in an impossible paradoxical position to respond and function across this country. Progressive adoption in each state of its own theory of liability which has extraterritorial application not only has a crushing effect on the pharmaceutical industry nation-wide, but also creates an almost certain liability spillover into different industries involving food additives, food preservatives, makers of dyes, to name but a few of those manufacturers whose products cross state borders on a massive scale.

There is no reasonable limitation for the precedent of cases which cast away "cause" as an essential element. An unimaginable number of products are consumed on a daily basis where verifiable source identification is destroyed in consumption, or by removal and discard of packaging. Further still, identity of components or separate ingredients of such products will be lost by merger or by use. If the justification for the Collins rule rests on the premise that an innocent plaintiff should be assured of a recovery when the product identity problem is "insurmountable", no national industry will be immune from imposition of the irrational presumption of liability inherent in the Collins rule.

More importantly, the pharmaceutical industry serves a very special role in mankind's search for methods to save lives and improve the quality of life. Continued expansion of new and differing forms of absolute liability in 50 separate states can only result in an atmosphere of fear and hesitation. Liability for negligence and defective products serves to protect the public from overzealousness in disseminating unsafe products, but industry-wide presumption of liability will delay and prohibit introduction of new medicines having value beyond calculation for those who

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Honorable United States Supreme Court. Though each petition should stand on its own right, we want to make this Court aware of a nationwide problem that the drug industry is facing, especially on the burdens of interstate commerce.

desperately need them. Every new wonder drug represents a step into the unknown, no matter how great the need, and despite the best efforts of scientists and the regulatory controls of the Food and Drug Administration. If the Collins rule is not violative of the United States Constitution, there may well be a need for repetitive legislation like that enacted for the swine flu vaccine.[3]

We urge upon this Honorable Court a recognition that *Collins* is a fountainhead from which wrongs will flow for years to come. A decision on the proposed constitutional issues will aid not only this Petitioner, but all who may later share in the disastrous consequences of the unconstitutional oppression woven into the Collins rule.

I

THE COLLINS MODIFIED RISK CONTRIBUTION THEORY IS A DEPRIVATION OF PETITIONER'S PROCEDURAL RIGHT TO DUE PROCESS OF LAW UNDER THE 14TH AMENDMENT TO THE UNITED STATES CONSTITUTION

The 14th Amendment procedural due process clause is a flexible principle to guarantee fundamental fairness on a federal and state level. In *Lassiter v. The Department of Social Services of Durham City,* 452 U.S. 18 (1981) this Court commented:

> "For all its consequences, 'due process' has never been, and perhaps can never be, precisely defined. '[U]nlike some legal rules,' this Court has said, due process 'is not a technical conception with a fixed content unrelated to time, place and circumstances.' *Cafeteria*

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[3]Swine Flu Act of 1976, 90 Stat. 1113 (amending 42 U.S.C. § 247(b)), insulating drug companies from products liability claims in order to insure production of the vaccine. See generally *Ducharme v. Merrill-National Laboratories,* 547 F.2d 1307 (1978), cert. denied, 439 U.S. 1002 (1978). Similar episodes are certain to arise with other drugs.

> *Workers v. McElroy,* 367 U.S. 886, 895, 81 S.Ct. 1743, 1748, 6 L.Ed.2d 1230. Rather, the phrase expresses the requirement of 'fundamental fairness,' a requirement whose meaning can be as opaque as its importance is lofty. Applying the Due Process Clause is therefore an uncertain enterprise which must discover what 'fundamental fairness' consists of in a particular situation by first considering any relevant precedents and then by assessing the several interests that are at stake."

The 14th Amendment procedural due process clause permeates every type of judicial process, including the constitutionality of *a state's tort remedies.* In *Parratt v. Taylor,* 451 U.S. 527, 537 (1981) this Court stated:

> "The Fourteenth Amendment protects only against deprivations 'without due process of law.' *Baker v. McCollan,* 443 U.S., at 145, 99 S.Ct., at 2695. Our inquiry therefore must focus on whether the respondent has suffered a deprivation of property without due process of law. In particular, *we must decide whether the tort remedies which the State of Nebraska provides as a means of redress for property deprivations satisfy the requirements of procedural due process.*" (Emphasis supplied)

Petitioner suggests that the Wisconsin Collins rule not only deviates from traditional tort law, but also results in a deprivation of procedural due process protections. A State Court created rule is subject to the same standards of due process as Wisconsin statutory legislation. *Chicago, Quincy & Burlington RR vs. Chicago,* 166 U.S. 226, at 241 (1897); and *New York Times v. Sullivan,* 376 U.S. 254 (1964).

The Collins rule is irrational and arbitrary in that it requires the finder of fact to presume causation from the mere manufacture of DES. As this Court stated with respect to criminal statutory presumptions in *Leary v. United States,* 395 U.S. 6, at 36 (1969), a presumption:

> ". . . must be regarded as 'irrational' or 'arbitrary' and hence unconstitutional, unless it can at least be said with substantial assurance that the presumed fact is more likely than not to flow from the proved fact on which it is made to depend." See also, *Speiser v. Randall*, 357 U.S. 513, 523 (1958).

Such a mandatory presumption creating tort liability can only be upheld as valid under the procedural due process clause *if* there is a rational connection between the fact established and the fact to be presumed. *Leary v. United States, supra.* If there is no such rational connection, due process of law is violated. See, also, *Turner v. Department of Employment, Security and Board of Review of the Industrial Commission of Utah*, 423 U.S. 44 (1975); *Stanley v. Illinois*, 405 U.S. 645 (1972); and *Cleveland Board of Education v. LaFleur*, 414 U.S. 632 (1974). In *Heiner v. Donnon*, 285 U.S. 312, at 329 (1932) this Court stated:

> "The Court has held more than once that a statute creating a presumption which operates to deny a fair opportunity to rebut it [the presumption] violates the due process clause of the Fourteenth Amendment."

The Collins rule does not offer an opportunity for exculpation in a meaningful way by showing that a given pharmaceutical company's product was not used by Plaintiff's mother—that is, Squibb did not make a 25 milligram white uncoated pill which Collins' mother *testified she ingested.* Despite the mother's evidence on drug identification, the Wisconsin Court still concluded that the Plaintiff, Therese Collins, was faced with *an insurmountable obstacle* by being unable to identify the manufacturer or distributor of the DES product ingested by her mother. Under this analysis, Petitioner must continue under the threat of potential liability with no assurance of exoneration, and under circumstances where causation does not even rise to the level of reasonable speculation.

Procedural due process requires that there be an opportunity to present every available defense. *Lindsey v. Normet,* 405 U.S. 56, 67 (1972); *American Surety Co. v. Baldwin,* 287 U.S. 156, 158 (1932). See, also, *Nickey v. State of Mississippi,* 292 U.S. 393, 396 (1934). A tort verdict bathed in such complete uncertainty is not consonant with procedural due process. *Western & Atlantic Railroad v. Henderson,* 279 U.S. 639 (1929); and *Matthews v. Eldridge,* 424 U.S. 319 (1976).

Petitioner would emphasize that the Wisconsin Court acknowledged in its decision that innocent defendants will be trapped in the web of liability created by the Collins rule. This acknowledgement leads unerringly to the conclusion that the Court is implementing a *rule not of fairness nor rationale,* but instead a rule to achieve a specific result under a philosophy that the end justifies the means. The Court made no attempt to disguise its goal of social engineering through judicial power. Its reasoning consists of a determination that it is better for drug companies to share the cost of Plaintiff's injury, and that the damage awards will be an incentive for adequate testing. (App. A p. 192). More likely than not, the effect will be fewer drugs produced at a higher cost, thus leaving open the real possibility that serious injury or death will occur to those whose disease or condition remains unchecked.

Petitioner asserts that the Collins rule does not afford Petitioner, nor the pharmaceutical industry with a "meaningful opportunity to be heard if it is to fulfill the promise of the due process clause." *Boddie v. Connecticut,* 401 U.S. 371, 379 (1971) (Harlan, J.).

II

THE COLLINS RULE VIOLATES PETITIONER SQUIBB'S RIGHTS TO SUBSTANTIVE DUE PROCESS OF LAW UNDER THE 14TH AMENDMENT TO THE UNITED STATES CONSTITUTION

The rule created by the Wisconsin Court destroys substantive rights to due process when viewed in the context of *substance over form*. This Court, in *Weaver v. Graham*, 450 U.S. 24, 31, fn. 15 (1981) stated that the Constitution deals with substance, not forms nor shadows.

> " 'The Constitution deals with substance, not shadows. Its inhibition was levelled at the thing, not the name. It intended that the rights of the citizen should be secure against deprivation for past conduct by legislative enactment, under any form, however, disguised.' *Cummings v. Missouri*, 4 Wall. 277, 325, 18 L.Ed. 356 (1867)."

Although a creation of the judiciary, the Collins rule, has all of the onerous characteristics of ex post facto legislation. It imposes substantive liability on innocent parties, and does so decades after the act they are charged with committing. They are presumed guilty, and will suffer a loss (punishment) under a rule which could not have been reasonably anticipated at the time of their involvement in the activities now assigned as wrongful. Entrapment of innocent parties was acknowledged by the Wisconsin Court in *Collins, supra*, p. 198, (App. A. p. A-25) as follows:

> ". . . This still could mean that some of the remaining defendants may be innocent, but we accept this as the price the defendants, and perhaps ultimately society, must pay to provide the plaintiff an adequate remedy under the law."

By shifting the burden of proof, Plaintiff's product identity problem is merely transposed to all of the innocent Defendants, who have even less opportunity to know or

learn the source of the product. Plaintiffs are thus encouraged to minimize or ignore any attempt at product identity. *Collins* clearly offers plaintiff the option to sue only a single defendant, or as many as they choose, forcing on any named defendant the unanswerable question whether to bring in additional defendants and carry plaintiff's burden in establishing that the added defendants produced "the type of DES" alleged to be involved.

Shifting the burden of proof effectively eliminates the only exculpatory defense available to Petitioner and other innocent defendants. In substantive terms, the end result of the Collins rule is to take the property of one pharmaceutical manufacturer to pay the liability of another. Any involuntary transfer of property must, in order to pass constitutional muster, afford the party prejudiced to due process of law—the sine qua non for such legal authority. The intrinsic essence of due process is for a defendant *to be given a realistic chance* to rebut the criminal charge or civil liability asserted against him. Substantive due process requires a fair trial before an impartial tribunal, *and then if* an adverse judgment be entered, the deprivation of defendant's property right.

The Collins rule suffers from the same inequities criticized by California dissenting Supreme Court Justice Richardson in *Sindell v. Abbott Laboratories, supra,* where Justice Richardson stated:

> "Although the majority purports to change only the required burden of proof by shifting it from plaintiffs to defendants, the effect of its holding is to guarantee that plaintiffs will prevail on the causation issue because defendants are no more capable of disproving factual causation than plaintiffs are of proving it. 'Market share' liability thus represents a new high water mark in tort law. The ramifications seem almost limitless, a fact which prompted one recent commentator, in criticizing a substantially identical theory, to

conclude that 'Elimination of the burden of proof as to identification [of the manufacturer whose drug injured plaintiff] would impose a liability which would exceed absolute liability.' Coggins, *Industry-Wide Liability* (1979) 13 Suffolk L.Rev. 980, 998, fn. omitted; see also pp. 1000-1001.) In my view, the majority's departure from traditional tort doctrine is unwise.

"The applicable principles of causation are very well established. A leading torts scholar, Dean Prosser, has authoritatively put it this way: 'An *essential* element of the plaintiff's cause of action for negligence, *or for that matter for any other tort,* is that there be some reasonable connection between the act or omission of the defendant and the damage which the plaintiff has suffered.' (Prosser, Torts (4th ed. 1971) § 41, p. 236, emphasis added.)"

"The majority attempts to justify its new liability on the ground that defendants herein are 'better able to bear the cost of injury resulting from the manufacture of a defective product.' (*Ante,* p. ..... [maj. opn., at p. 30]. This 'deep pocket' theory of liability, fastening liability on defendants presumably because they are rich, has understandable popular appeal and might be tolerable in a case disclosing substantially stronger evidence of causation than herein appears. But as a general proposition, a defendant's wealth is an unreliable indicator of fault, and should play no part, at least consciously, in the legal analysis of the problem. In the absence of proof that a particular defendant caused or at least probably caused plaintiff's injuries, a defendant's ability to bear the cost thereof is no more pertinent to the underlying issue of liability than its 'substantial' share of the relevant market. *A system priding itself on 'equal justice under law' does not flower when the liability as well as the damage aspect of a tort action is determined by a defendant's wealth.*" (Emphasis supplied).

If permitted to stand, the precedent of the Collins rule will continue to trample upon fundamental substantive rights of litigants in derogation of the 14th Amendment. This Court, as the court of last resort, should harness the unbridled effects generated by the Collins rule.

III

THE COLLINS RULE VIOLATES THE EQUAL PROTECTION CLAUSE OF THE 14TH AMENDMENT TO THE UNITED STATES CONSTITUTION

Petitioner Squibb submits that any judicially established rule allowing a plaintiff to recover against one or more pharmaceutical manufacturers without product identification and tracing constitutes a denial of equal protection of the law. A rule dispensing with proof of cause-in-fact was created for DES cases, but not applicable in all other tort cases, except "situations which are factually similar" (App. A p. 191). Equal protection of the law insures a party's right to have his case tried and determined *in like manner and procedure with that of other defendants similarly situated.* The inability of some plaintiffs to bear the uniformally established burden of proof in tort law does not justify dispensing with that burden in an arbitrarily select group of cases. The possible inability of the Plaintiff Collins to prove her case cannot be blamed on any conduct of Petitioner Squibb nor any other pharmaceutical manufacturer. The Wisconsin Court chose to describe the product identity problem for *Collins* as an "insurmountable obstacle." The record, however, establishes that Plaintiff attempted to amend her complaint to name Eli Lilly & Company as the manufacturer involved, and presumably was prepared to offer proof on this issue to the trier of fact. If a requirement for proof of cause-in-fact is eliminated for only one type of product, or only one class of manufacturer, then an unconstitutional discrimination occurs with a class of manufacturers who are treated in a manner unlike the standards of justice applied to all other defendants.

The purpose of the law of tort is not to provide plaintiffs with compensation, but to give a form of equally fair consideration to claims and defenses. Equal protection demands that *all* tort plaintiffs and all tort defendants be given the same equal chance to prove or disprove claims, and not to assure that one side always emerges victorious. The Collins rule is not rationally related to securing a fair trial for all tort litigants. See *Dandridge v. Williams,* 397 U.S. 471 (1970); and *Weinberger v. Salfi,* 422 U.S. 749 (1975). The imposition of the Collins rule upon Petitioner Squibb is merely the transfer of property on the basis of social conscience (in its best light) or an attempt to punish Petitioner Squibb for manufacturing a synthetic estrogen (in its worst). Petitioner Squibb is entitled to equal protection of the law, even if the deprivation is created by a ruling of a state Court. See *New York Times Co. v. Sullivan,* 376 U.S. 254 (1964). The advancement of the principles of tort, just like any other rule of law, must stop at the border of the equal protection clause.

IV

ARTICLE I, SECTION 9 OF THE WISCONSIN CONSTITUTION HAS BEEN UNCONSTITUTIONALLY APPLIED BY THE WISCONSIN SUPREME COURT IN DEPRIVATION OF PETITIONER'S 14TH AMENDMENT RIGHTS BY CREATION OF THE COLLINS RULE

Article I, Section 9 of the Wisconsin Constitution provides:

> "Section 9. Every person is entitled to a certain remedy in the laws for all injuries, or wrongs which he may receive in his person, property, or character; he ought to obtain justice freely, and without being obliged to purchase it, completely and without denial, promptly and without delay, comformably to the laws."

The Wisconsin Supreme Court historically has interpreted this constitutional provision as not providing the courts with the right to fashion a remedy for the purpose of assuring a claimant's recovery. In *Neuhaus v. Clark County,* 14 Wis. 2d 222, 229, 111 N.W. 2d 180 (1961), the prior members of the Wisconsin Supreme Court interpreted Article I, Section 9 *as merely providing a suitor his day in court and not a guarantee of a remedy to be accompanied by a certain recovery.*

In *New York Life Ins. Co. v. State,* 192 Wis. 404, 412, 211 N.W. 288, error dismiss, 276 U.S. 602 (1927), the Wisconsin Supreme Court stated:

> "The guaranty of sec. 9, art. I of the state constitution that 'Every person is entitled to a certain remedy in the laws' does not mean a remedy that must be accompanied by a certainty of recovery. *If it did, the losing party of every lawsuit would be denied rights guaranteed to him by this section of the constitution. This provision does no more than to guarantee to every suitor his day in a court of competent claim for judicial relief and in which the jurisdiction to which he may present his may either win a victory or suffer a defeat according to the strength or weakness of the case which he presents.*" (Emphasis supplied).

The current Justices of the Wisconsin Supreme Court in *Mulder v. Acme-Cleveland Corp.,* 95 Wis. 2d 173, 189, 290 N.W. 2d 276 (1980) stated:

> "That section, though of great importance in our jurisprudence, is primarily addressed to the right of persons to have access to the courts and to obtain justice on the basis of the law as it in fact exists. No legal rights are conferred by this portion of the Constitution."

> " 'They do not grant the right, but guarantee the preservation of one that existed under the constitution of England.' " (Fn. 3)

The Collins decision did not overrule, modify nor distinguish any of the prior Wisconsin Supreme Court decisions interpreting Article I, Section 9. Instead, reference to this provision was offered in support of the meritorious doctrine that Wisconsin's highest court is permitted to expand the common law *when an adequate remedy or forum does not exist to resolve disputes or provide due process.* (App. A p. 182) This cannot mean, however, a boundless authority to retroactively destroy the constitutional protections of a selected group of citizens in a discriminatory manner.

Formulating a rule "for plaintiffs in DES cases in Wisconsin" and "in situations which are factually similar to the DES cases" (App. A p. 191) is not in reality an expansion of the common law. It is instead a deviant exception to existing law, under a standard so vague that reasonable minds cannot hope to agree on the classes or numbers of citizens who may also receive the *special treatment* given Petitioner and other members of its industry under the Collins rule.

Plaintiff Collins has always had access to the Wisconsin courts, and has not been hindered in her opportunity to obtain justice "on the basis of the law as it in fact exists." If the Collins court intended to brace its decision on this provision of the Wisconsin Constitution, they have radically changed their own view of what this provision means. Under any view, however, they have gone too far when they develop a special rule which denies equal protection and due process of law to Petitioner and other members of the pharmaceutical industry.

V

THE COLLINS RULE VIOLATES THE SUPREMACY CLAUSE OF THE UNITED STATES CONSTITUTION AND IMPERMISSIBLY INTERFERES WITH INTERSTATE COMMERCE

The national policy is to foster the availability to the public of low cost generic or "me-too" drugs. Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), as amended, 21 U.S.C. §§ 301, *et seq; Abbott Laboratories v. Gardner,* 387 U.S. 136, 138 (1967). Accordingly, FDA has promulgated regulations to encourage the sale of "identical, related, or similar drugs." 21 C.F.R. § 306.1(b) (1979).

Congress has entrusted the administration of national drug policy—and its purpose of fostering the public's interest in "drugs that are useful in the prevention, control, or treatment of illness," *Weinberger v. Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 639 n.2 (1973) (Powell, J., concurring)—to a centralized federal agency, the FDA. Congress has chosen the FDA to be the decision maker in this area, and its judgments in approving a drug as safe for use must be beyond private scrutiny and litigation. *Gray v. United States, supra.*

In rejecting the concerted action, enterprise, and civil conspiracy theories advanced by Collins, the Wisconsin Court recognized the pervasive role of the federal government in the testing and marketing of drugs. These theories were found inappropriate in part because they rest on a premise that the manufacturers could control standards at an inadequate level. All members of the drug industry, however, must operate under the control of the FDA, which sets the standards and conditions manufacturers must meet to produce and market a particular drug. No reason is suggested, though, why this regulatory scheme may be ignored in the adoption of Wisconsin's new rule. The conflict with federal drug policy is actually more severe under the Col-

lins rule, where industry-wide presumed liability is imposed for mere status as a manufacturer of a drug approved by the FDA as safe.

Clearly, the holding in Collins frustrates and interferes with federal drug policy when it allocates presumed liability to all members of a federally regulated industry even though each had fully complied with all federal regulations, and for no reason other than the fact that they produced and sold the approved drug.

The Wisconsin Collins rule also imposes an impermissible burden on interstate commerce in violation of Article I, Section 8 of the United States Constitution. Although this rule originates from a claim involving drug companies, the same "insurmountable obstacle" which prompts the rule will exist for many different products. The question is thus raised whether the State of Wisconsin can render meaningless the constitutional protection of corporate citizens in 49 other states against being forced to come to Wisconsin and defend claims for no better reason than the fact that they are producers of a "type of product" which is alleged to have harmed a Wisconsin plaintiff. Carried to its extreme, this state action not only violates rights of those citizens, but also impacts upon a federal policy to promote the free exercise of commerce between states. The commerce clause is there not only to protect the instrumentalities of interstate commerce, but also persons or things in commerce and to prevent undue burdens on activities affecting commerce. See *Hodel v. Virginia Surface Mining & Reclamation Assoc.*, 452 U.S. 264, 276-77 (1981); and *Edgar v. Mite Corp.*, 457 U.S. 624 (1982).

This Court has consistently held that a defendant may not be compelled to litigate in a state when the effect of the litigation would be to unduly burden interstate commerce, even though there may be a sufficient jurisdictional presence for purposes of the Due Process Clause. *Denver & R.G.W.*

RR v. Terte, 284 U.S. 284 (1932); *Michigan Central RR v. Mix*, 278 U.S. 492 (1929); *Atchison, T. & S.F. RR v. Wells*, 265 U.S. 101 (1924); *Davis v. Farmers' Cooperative Equity Co.*, 262 U.S. 312 (1923). The Court has never cast a shadow on these cases, and their continued vitality has been assumed by some of our most distinguished federal judges. See *Scanapico v. Richmond, F. & P. RR*, 439 F.2d 17, 25-28 (2d Cir. 1970) (*en banc*) (Friendly, J.); *Erlanger Mills, Inc. v. Cohoes Fibre Mills, Inc.*, 239 F.2d 502 (4th Cir. 1956) (Sobeloff, J.).

In the cases cited above, the cause of action was understood to have "arisen" outside the state, under the prevailing jurisprudence of the time, but this point should not be controlling. The question of whether there has been an undue interference with interstate commerce should not turn on the talismanic point of whether or not the cause of action "arose" within the state—especially in this mobile 20th century.

If it is true that the Collins rule will inevitably extend to other types of products and other industries, the potential for unreasonable burdens on interstate commerce can hardly be exaggerated. Similarly, Collins is but one of several new theories adopted by different states which have instilled great concern among members of the pharmaceutical industry. This concern arises from a perception of unfair treatment, and tends to discourage development and marketing of a product vital to the health and well-being of all citizens. The Collins rule together with other new theories adopted by sister states have created an undue burden on commercial activities of the pharmaceutical industry.

CONCLUSION

Adoption of an industry-wide risk contribution theory together with abolition of a requirement for proof of cause-in-fact is a concept no less flawed than star-chamber proceedings when weighed on the scales of constitutional measure. Presumption of liability combined with almost certain inability of many innocent defendants to escape this maze cannot be blended with a system of justice guaranteed under the United States Constitution.

Petitioner Squibb respectfully prays that this United States Supreme Court grant its Petition for Writ of Certiorari and allow the issuance of said Writ.

Respectfully submitted:

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(Appendices follow)

Appendix A

Opinion of Wisconsin Supreme Court
Therese Marie Collins, now known as Therese Marie Gastrow, Plaintiff-Appellant,

v.

Eli Lilly Company; Rexall Drug Company; E.R. Squibb & Sons, Inc.; et al., Defendants-Respondents

APPEAL from a judgment and an order of the Circuit Court for Milwaukee County: MARVIN C. HOLZ, JUDGE. *Reversed in part, affirmed in part, and remanded.*

WILLIAM G. CALLOW, J. This is an appeal from a judgment and an order of the circuit court for Milwaukee county, Judge Marvin C. Holz, granting summary judgment for the defendant drug companies and denying the plaintiff's motion to amend her second amended complaint to identify as a sole defendant Eli Lilly and Company. The plaintiff appealed and petitioned to bypass the court of appeals pursuant to sec. 808.05 and sec. (Rule) 809.60, Stats. We granted the petition to bypass. We reverse in part and affirm in part the judgment of the trial court granting summary judgment for the defendants, and we remand the case for further proceedings. We affirm the order of the trial court denying the plaintiff's motion to amend her second amended complaint.

The issues presented on appeal are whether the trial court erred in granting summary judgment for the defendants based upon its conclusion that no Wisconsin rule of law would permit the plaintiff to recover for her injuries stemming from her mother's ingestion of the drug diethylstilbestrol (DES), and whether the trial court erred in not permitting the plaintiff to amend her second amended

complaint to name a single drug company, Eli Lilly and Company, as defendant.[1]

In 1957 Mrs. Roseann Collins became pregnant with Therese Marie Collins, the plaintiff in this case. Because Mrs. Collins was having problems with spotting in the early stages of her pregnancy, she consulted her physician, Dr. William P. Wendt. Sometime in the course of his treatment of Mrs. Collins, Dr. Wendt prescribed DES, which he told her would prevent a miscarriage. Mrs. Collins took DES throughout her pregnancy. Mrs. Collins could not recall where she purchased the DES but did recall, without being certain, that "it was a little white [uncoated] pill . . . smaller than an aspirin." Information adduced in the course of discovery revealed that the DES Mrs. Collins took was in the form of 25 milligram pills. The plaintiff was born March 11, 1958, in Milwaukee.

In June or July, 1975, the plaintiff began to experience longer than normal menstrual periods accompanied by severe cramping. On July 24, 1975, Mrs. Collins took the plaintiff to consult Dr. Wendt. During the examination Dr. Wendt discovered a visible lesion in the plaintiff's vagina. Dr. Wendt referred the plaintiff to Dr. William Fetherston for further diagnosis. After examining the plaintiff, Dr. Fetherston concluded that she was suffering from a full cell cancer of the vagina. On August 26, 1975, Dr. Fetherston performed surgery on the plaintiff, removing her uterus, part of her vagina, and a number of lymph nodes. Subsequent analysis by Dr. David Carlson, a patho-

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[1]The defendants cross-appealed on the issue whether the plaintiff's cause of action was barred by the running of the statute of limitations, sec. 893.205, Stats., 1975. However, on August 4, 1983, the defendants, pursuant to sec. (Rule) 809.18, Stats., voluntarily dismissed their cross-appeal on the basis of this court's decision in *Hansen v. A.H. Robins Co., Inc.*, 113 Wis. 2d 550, 335 N.W.2d 578 (1983).

logist at St. Mary's Hospital in Milwaukee, confirmed that the plaintiff had adenocarcinoma of the vagina and benign adenosis of the vagina. Subsequent to the surgery, the plaintiff discovered that her bladder had ceased functioning because of the radical cancer surgery.

On January 6, 1977, the plaintiff filed suit against twelve drug companies which allegedly produced or marketed DES. On November 21, 1977, Judge William R. Moser granted defendants Lilly, Rexall, Squibb, and Abbott's motion to dismiss on the grounds of improper service. On February 28, 1978, the plaintiff filed a second amended complaint, naming five additional drug companies as defendants, and this time effectuated proper service on all defendants.

The plaintiff's second amended complaint alleged five causes of action: that the defendants were negligent in producing and marketing DES for use by pregnant women; that the defendants were strictly liable because DES was a defective and unreasonably dangerous product; that the defendants misrepresented that DES was safe and efficacious for use by pregnant women; that the defendants conspired to misrepresent that DES was safe and efficacious for use by pregnant women; that the defendants acted as a class in manufacturing and marketing DES.[2] The plaintiff demanded $3 million in compensatory damages, together with $3 million in punitive damages.

On May 26, 1981, the defendants jointly moved the court, pursuant to sec. 802.08, Stats., for summary judgment in

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[2]In her fifth cause of action, the plaintiff realleges her other causes of action and then alleges that all DES drug companies, whether joined in this case or not, engaged in similar actionable conduct in producing and marketing DES. We conclude that this cause of action does not state a separate claim upon which relief may be granted, and, therefore, the trial court correctly granted summary judgment as to the plaintiff's fifth cause of action.

their favor alleging that there was no genuine issue as to any material fact and that Wisconsin law provided no remedy for the plaintiff based upon the factual record. The defendants also individually moved for summary judgment, variously alleging that the statute of limitations barred recovery, that the defendant drug company had not manufactured or marketed DES in the relevant form, time period, or geographical area, or that the plaintiff's theory of recovery was not recognized under current law.

On April 23, 1982, Judge Marvin C. Holz rendered a memorandum decision on the defendants' joint summary judgment motion. The court granted the motion for summary judgment after examining various theories proposed by the plaintiff to avoid the problem of the plaintiff's inability to identify which defendant drug company produced or marketed the DES taken by her mother. The court concluded that all the theories would necessitate a radical departure from current law, and that if such a departure were appropriate, it should be decided by this court. Accordingly, on September 16, 1982, the trial court entered judgment dismissing the plaintiff's second amended complaint.

On May 20, 1982, the plaintiff filed a motion requesting permission to amend her second amended complaint if she did not appeal from the summary judgment decision of April 23, 1982, or if she appealed and the summary judgment was affirmed. The plaintiff wanted to amend her second amended complaint to name Eli Lilly as the sole defendant on the grounds that there was a reasonable probability that it manufactured the DES taken by the plaintiff's mother. In a memorandum decision dated August 9, 1982, the trial court concluded that the requested amendment was not appropriate because the plaintiff was not alleging any new facts which would support her recently asserted allegation that one drug company manufactured DES. The trial court entered an order denying the plain-

tiff's motion to amend on August 23, 1982. The plaintiff filed an appeal from the judgment entered September 16, 1982, and the order entered August 23, 1982.

The problem facing Therese Collins, who alleges injury by in utero exposure to DES, is that she is unable to identify the precise producer or marketer of the DES taken by her mother due to the generic status of some DES, the number of producers or marketers, the lack of pertinent records, and the passage of time. Several courts have applied existing theories of law or crafted new theories to permit DES plaintiffs to avoid the almost insurmountable obstacle of proving that a particular drug company produced or marketed the DES which caused them injury.[3] Other courts have simply denied DES plaintiffs recovery because existing tort law requires plaintiffs to prove that a particular defendant caused the plaintiffs' harm.[4] In determining our approach to this problem, it is appropriate to set forth the factual background against which the issues in this case cannot be analyzed.

DES is a synthetic estrogenic hormone which duplicates the activity of estrogen, a female sex hormone present in all women and, to a lesser extent, also in men. In women, estrogen is one of the hormones crucial to female sexual development and fertility.

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[3]*See, e.g., Sindell v. Abbott Laboratories,* 26 Cal. 3d 588, 163 Cal. Rptr. 132, 607 P.2d 924 (1980); *McElhaney v. Eli Lilly & Co.,* 564 F. Supp. 265 (D. S.D. 1983); *Bichler v. Eli Lilly and Co.,* 55 N.Y.2d 571, 436 N.E.2d 182 (1982); *Abel v. Eli Lilly and Co.,* 94 Mich. App. 59, 289 N.W.2d 20 (1979).

[4]*See, e.g., Morton v. Abbott Laboratories,* 538 F. Supp. 593 (M.D. Fla. 1982); *Payton v. Abbott Labs.,* 512 F. Supp. 1031 (D. Mass. 1981); *Ryan v. Eli Lilly & Co.,* 514 F. Supp. 1004 (D. S.C. 1981); *Lyons v. Premo Pharmaceutical Labs, Inc.,* 170 N.J. Super. 183, 406 A.2d 185 (1979); *Gray v. United States,* 445 F. Supp. 337 (S.D. Tex. 1978).

In the late 1930's, DES was synthesized by a group of British medical researchers, but the drug formula was not patented and, therefore, remained in the public domain. In 1939 and 1940, several drug companies became interested in producing and marketing DES. In order for these companies to produce and market DES for medical use in the United States, they had to file a New Drug[5] Application (NDA) with, and obtain approval of, the Federal Food and Drug Administration (FDA). *See* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 717, 52 Stat. 1040, sec. 201(p) (1938).

By the end of 1940, ten drug companies had filed NDA's requesting authorization to produce and market DES for four purposes: treatment of menopausal symptoms, senile vaginitis, gonorrheal vaginitis, and suppression of lactation. None of the purposes related to use in problems of pregnancy.

In late 1940, the FDA determined that it would be appropriate for the drug companies to pool their clinical data into a "master file" which the FDA would use as the data base for their decision on the NDA's for DES. Accordingly, in early 1941 several drug companies formed a "small committee" to collect the data accumulated by each of the drug companies filing an NDA for approval of DES. This joint clinical data was included in each company's resubmission of an NDA to produce and market DES for the above-mentioned purposes. In September 1941, the FDA

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[5]The term "new drug" is defined as: "Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof." Federal Food, Drug, and Cosmetic Act, Pub. L. No. 717, 52 Stat. 1040, 1041-42, sec. 201(p)(1) (1938) [codified as amended at 21 U.S.C. sec. 321 (p)(1) (1976)].

approved the pending NDA's for the production and marketing of DES.

In the 1930's, independent researchers began conducting studies on the role of hormones in pregnancy. These researchers found that the administration of estrogen in certain problem pregnancies appeared to help prevent miscarriages by keeping hormonal levels constant during pregnancy. Thus, when an inexpensive, abundant source of estrogen became available in the form of DES, the researchers switched from using natural estrogen to synthetic DES. Based on articles published in the early and mid-1940's containing these researchers' findings on the possible use of DES in preventing miscarriages in problem pregnancies, several drug companies became interested in producing and marketing DES for this newly discovered purpose.

During 1947 and 1948, several drug companies separately filed supplemental NDA's requesting the FDA's approval to produce and market a 25 milligram size of DES for use in problem pregnancies. Most, if not all, of the supplemental NDA's relied on clinical studies published in medical journals, but there is no indication that the companies had any direct connection with the independent researchers. Also, there is no indication that the drug companies worked closely together when they filed their supplemental NDA's. The first supplemental NDA's were reviewed and approved by the FDA during 1947; thereafter, as supplemental NDA's were filed, they were routinely approved. In 1952 the FDA decided that DES was no longer a "new drug," thereby permitting drug companies to produce and market DES for use in pregnancy without having to file NDA's.

DES was produced and marketed from 1947 to 1971. In 1971 medical researchers established a possible statistical link between fetal exposure to DES during pregnancy and

the development many years later of adenocarcinoma of the vagina.[6] *See* Note, *Proof of Causation in Multiparty Drug Litigation,* 56 Tex. L. Rev. 125, 126 n. 11 (1977); Note, *Market Share Liability: An Answer to the DES Causation Problem,* 94 Harv. L. Rev. 668, 669 n. 8 (1981) [hereinafter cited as Note, *Market Share Liability*]. In late 1971, the FDA ordered that drug companies label DES as contraindicated for use in pregnancy. 36 Fed. Reg. 21,537-38 (1971).

As noted earlier, the crux of the problem facing this DES plaintiff, and probably many others, is that she cannot identify the drug company that she alleges caused her injury. Numerous commentators and courts have identified several reasons for this plight. First, DES was, for the most part, produced in a "generic" form which did not contain any clearly identifiable shape, color, or markings. DES was a fungible drug produced with a chemically identical formula, and often pharmacists would fill DES prescriptions from whatever stock they had on hand, whether or not a particular brand was specified in the prescription.

Second, it has been estimated that possibly as many as three hundred drug companies produced or marketed DES during the twenty-four years DES was on the market, with different companies entering and leaving the market throughout this period. In this case, the defendants have produced evidence that during 1957 and 1958, the years DES was prescribed for the plaintiff's mother, at least one hundred twenty companies marketed DES in the 25 milligram size. The plaintiff has countered with assertions that

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[6]The claims that DES was effective in preventing miscarriages were questioned by later medical studies. *See, e.g.,* Dieckmann, Davis, Rynkiewicz and Pottinger, *Does the Administration of Diethylstilbestrol During Pregnancy Have Therapeutic Value?,* 66 Am. J. Obstet. & Gynec. 1062 (1953). Obviously, this information was available to the drug companies, but they nonetheless continued producing and marketing DES for use in pregnancy until it was banned in 1971.

the bulk manufacture of DES was dominated by only a few companies. Nevertheless, there may be many companies, both producers and marketers, that share potential liability for the plaintiff's injuries.

Third, it appears that many drug companies may not have kept or may not be able to locate pertinent records as to when, where, and what type of DES they produced or marketed. Similarly, this plaintiff, and probably others, does not have records identifying the type of DES prescribed for and taken by her mother. These problems result from the passage of many years between the plaintiff's in utero exposure and the manifestion of cancer. During the intervening years, memories may have faded, medical and pharmaceutical records may have been lost or destroyed, and witnesses may have died.

By the time that DES was banned for use in pregnancy in 1971, many women already had been exposed to DES during their mothers' pregnancies.[7] Reliable estimates placed the number of individual or class action DES suits then pending at approximately 1,000. *See* Note, *Market Share Liability,* at 669. It is probable, given the sheer number of potential victims, that many more suits will arise. Thus, it is quite clear that in this case we are not dealing with an isolated, unique set of circumstances which will never occur again. We are faced with a choice of either fashioning a method of recovery for the DES case which will deviate from traditional notions of tort law, or permitting possibly negligent defendants to escape liability to an innocent, injured plaintiff. In the interests of justice and fundamental fairness, we choose to follow the former alternative.

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[7]In this case, alone, Dr. Wendt, the physician treating the plaintiff's mother, estimated that he had over the course of his career prescribed DES in five hundred pregnancies.

We note at the outset that the common law tort rule requires that a plaintiff prove not only duty, breach of duty, and injury, but also legal causation between a defendant's conduct and a plaintiff's injury. *See Fondell v. Lucky Stores, Inc.*, 85 Wis. 2d 220, 226-28, 270 N.W.2d 205 (1978). [To recover, Therese Collins would have to prove that a particular drug company produced or marketed the DES taken by her mother. As we noted earlier, this proof is an insurmountable obstacle for Therese Collins even if she can establish all the remaining elements of her cause of action.]

Article I, sec. 9 of the Wisconsin Constitution provides, in part, that "[e]very person is entitled to a certain remedy in the laws for all injuries, or wrongs which he may receive in his person, property, or character." We have interpreted this provision of the constitution in the following manner: " 'When an adequate remedy or forum does not exist to resolve disputes or provide due process, the courts, under the Wisconsin Constitution, can fashion an adequate remedy.' " *In Interest of D.H.*, 76 Wis. 2d 286, 294, 251 N.W.2d 196 (1977) (citation omitted). We have recognized that:

"[i]nherent in the common law is a dynamic principle which allows it to grow and to tailor itself to meet changing needs within the doctrine of *stare decisis*, which, if correctly understood, was not static and did not forever prevent the courts from reversing themselves or from applying principles of common law to new situations as the need arose."

Bielski v. Schulze, 16 Wis. 2d 1, 11, 114 N.W.2d 105 (1962). Because we conclude Therese Collins is entitled to a remedy at law for her injuries, we now consider each of the theories proposed in this appeal to support her right to recovery.

Therese Collins first proposes that we adopt the "alternative liability" theory enunciated in *Summers v. Tice*, 33 Cal. 2d 80, 199 P.2d 1 (1948), holding the defendants liable without requiring the plaintiff to prove the identity of a

specific tortfeasor. In *Summers* two hunters negligently shot in the direction of the plaintiff, but it could not be ascertained which hunter's bullet injured the plaintiff. In response to the plaintiff's inability to identify the actual tortfeasor, the court developed a theory, which is summarized as follows:

"Where the conduct of two or more actors is tortious, and it is proved that harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one of them has caused it, the burden is upon each such actor to prove that he has not caused the harm."

Restatement (Second) of Torts sec. 433B(3) (1965). Thus, under this theory when all defendants, although acting independently, have breached a duty of care toward the plaintiff but only one of them caused the injury, each defendant must prove that he or she did not cause the plaintiff's injury or be jointly and severally liable with all other defendants. In effect, the burden of proof as to causation shifts to each defendant who must prove that he or she did *not* cause the plaintiff's injuries. This rule represents a policy determination that an innocent plaintiff should not be without remedy because he or she is unable to prove which of the negligent defendants caused the harm. *See Summers,* 33 Cal. 2d at 86-88, 199 P.2d at 4-5.

We agree with the commentators and courts that have concluded the alternative liability theory does not present a viable theory for DES cases. First, the alternative liability theory is, in part, premised on the assumption the defendants will be "in a far better position [than the plaintiff] to offer evidence to determine which one caused the injury." *Summers,* 33 Cal. 2d at 86, 199 P.2d at 4. In this case, both the plaintiff and the defendants have problems with access to information about DES production and marketing. Second, the alternative liability theory formulation contemplates that all negligent defendants will be joined in the

suit. Thus, the court can be sure that at least one of the defendants was directly responsible for the plaintiff's harm. In a DES case, however, there may be hundreds of defendants that may be liable, and, therefore, the probability that any one defendant caused the plaintiff's harm may be correspondingly small. *See Sindell v. Abbott Laboratories,* 26 Cal. 3d 588, 602-03, 163 Cal. Rptr. 132, 139, 607 P.2d 924, 931 (1980). Moreover, it may be impossible to identify all DES producers or marketers because of the fluid nature of the market over the years DES was produced or marketed for use in pregnancy. Third, the alternative liability formula does not, in its pure form, provide a fair way to apportion damages among the defendants. Under the alternative liability theory, defendants that produced or marketed small amounts of DES and those that produced or marketed large amounts would be equally liable.

The plaintiff next asks this court to adopt the "concerted action" theory of liability. Under this theory there are three variants: pure concerted action, "enterprise liability," and, as the plaintiff has alleged in this case, civil conspiracy.

The concerted action theory of liability rests upon the principle that "those who, in pursuance of a common plan or design to commit a tortious act, actively take part in it, or further it by cooperation or request, or who lend aid or encouragement to the wrongdoer, or ratify and adopt his acts done for their benefit, are equally liable with him. Express agreement is not necessary, and all that is required is that there be a tacit understanding." W. Prosser, *Handbook of The Law of Torts,* sec. 46 at 292 (4th ed. 1971) (footnotes omitted). *See also* Restatement (Second) of Torts sec. 876 (1979). Although this court has not explicitly adopted the Restatement rule, we have applied a variant of the theory in "drag racing" cases which imposed joint and several liability on all defendants participating in a drag race even if only one of the defendants actually caused the plaintiff harm. *See, e.g., Ogle v. Avina,* 33 Wis. 2d 125, 134-35, 146 N.W.2d 422 (1966).

Even assuming that the defendants acted tortiously toward the plaintiff, the plaintiff, under the concerted action theory of liability, must also be able to prove that there was an agreement or, at least, a tacit understanding among the defendants. In this case, the "gravamen of the charge of concert is that defendants failed to adequately test [DES] or to give sufficient warning of its dangers and that they relied upon the tests performed by one another and took advantage of each others' promotional and marketing techniques." *Sindell,* 26 Cal. 3d at 605, 607 P.2d at 932. We agree with the California court's conclusion in *Sindell* that such allegations do not support the theory that the defendants tacitly agreed to produce and market DES without adequately testing the drug or warning of its potential dangers. Although there was a substantial amount of parallel action by the defendants in producing and marketing DES for use in pregnancy, we conclude that this does not rise to the level of "acting in concert."

We also note that the conceptual underpinnings of the concerted action theory make it inapplicable to DES cases. The concerted action theory typically is applied to situations in which, unlike this DES case, a particular defendant is already identified as causing the plaintiff's harm, and the plaintiff desires to extend liability to those acting in league with that defendant. Comment, *Overcoming the Identification Burden in DES Litigation: The Market Share Liability Theory,* 65 Marq. L. Rev. 609, 618 (1982). The theory rarely has been used to help plaintiffs avoid the identification requirement, Note, *DES: Judicial Interest Balancing and Innovation,* 22 B.C. L. Rev. 747, 759-60 (1981), and we decline to do so in this case.

Another variant of the concerted action theory of liability is found in the concept of industrywide, or "enterprise liability," which was first suggested in *Hall v. E.I. Du Pont De Nemours & Co., Inc.,* 345 F. Supp. 353 (E.D. N.Y.

1972). *Hall* involved persons who had been injured by blasting caps manufactured by a limited number of defendants under substantially similar industry-imposed safety standards. The court reasoned that such evidence could support a finding that the defendants jointly controlled the risk of harm, and therefore, the issue of which defendant actually caused the plaintiff's harm became less important than the fact that the industry as a whole engaged in hazardous conduct. *Id.* at 374, 372. Under enterprise liability theory, it is the industry-wide standard that is the cause of injury, and each defendant that participates in perpetuating and using the inadequate standard has contributed to and is liable for the plaintiff's injury. *See* Comment, *DES and A Proposed Theory of Enterprise Liability,* 46 Fordham L. Rev. 963, 997 (1978).

We conclude that the enterprise liability theory should not be applied in this case. First, unlike *Hall,* this case involves perhaps hundreds of potential defendant drug companies. Thus, the assumption that the defendants jointly controlled the risk of injury is necessarily weak given the fact that so many drug companies entered and left the DES marketplace from 1947 to 1971.[8] Second, the drug industry operates under the control of the FDA, which sets the standards and conditions the drug industry must meet to produce and market a particular drug. It is less clear in DES cases than in *Hall* that the defendant drug companies were each violating a standard of safety, whether federally imposed or industry imposed, in producing and marketing DES for use in pregnancy. We recognize, however, that

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[8]Indeed, the court in *Hall* cautioned against using enterprise liability for large numbers of defendant companies, stating that "[w]hat would be fair and feasible with regard to an industry of five or ten producers might be manifestly unreasonable if applied to a decentralized industry composed of thousands of small producers." *Hall v. E.I. Du Pont De Nemours & Co., Inc.*, 345 F.Supp. 353, 378 (E.D. N.Y. 1972).

adherence to FDA standards does not in itself absolve a drug company of liability. *See Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65, 107 Cal. Rptr. 45, 53, 507 P.2d 653, 661 (1973).

Finally, the plaintiff in this case relies on the theory of civil conspiracy, alleging that the defendants conspired to misrepresent that DES was safe and efficacious for use in pregnancy. A civil conspiracy is "a combination of two or more persons by some concerted action to accomplish some unlawful purpose or to accomplish by unlawful means some purpose not in itself unlawful." *Radue v. Dill*, 74 Wis. 2d 239, 241, 246 N.W.2d 507 (1976) (citation omitted). The plaintiff asserts that the defendant drug companies formed and operated a conspiracy to gain FDA approval of DES in 1941 and then carried the conspiracy into seeking FDA approval in 1947 and 1948 for use of DES in problem pregnancies. Then, the plaintiff contends, the drug companies used the fruits of their conspiracy, i.e., FDA approval to produce and market DES for pregnancy, to misrepresent to the public at large, including the plaintiff's mother, that DES was safe and efficacious.

We conclude that an action for civil conspiracy cannot be pursued on the allegations made in this case. As we noted earlier, the drug companies apparently engaged in parallel behavior in both 1941 and 1947, but parallel behavior alone cannot prove agreement. There is no indication in the record that the defendants either explicitly or tacitly collaborated to gain FDA approval so that they could in turn collaborate to misrepresent the safety and efficacy of DES for use in preventing miscarriages. Even assuming that there was close enough cooperation in 1941 to constitute an agreement, we cannot conclude that the agreement extended to the filing of supplemental NDA's in 1947 and 1948. Further, this theory becomes unworkable when we consider the fact that many drug companies entered the DES market well after FDA approval. These

later entrants should not be charged with participation in or knowledge of the alleged 1941 and 1947 conspiracies.

The final theory proposed by the plaintiff is the "market share" theory adopted by the California Supreme Court in *Sindell v. Abbott Laboratories, supra. Sindell* applied "a modification of the rule of *Summers*" and fashioned an apportionment of liability based on the relative market share of each of the liable defendants. In *Sindell* the court held that, once the plaintiff joins manufacturers of a "substantial share" of the DES produced and marketed in the relevant area and proves a prima facia case on every element except identification of the direct tortfeasor, the burden of proof shifts to the defendants to prove that they did not cause the plaintiff's injuries. *Sindell,* 26 Cal. 3d at 612, 607 P.2d at 937. This can be done by each defendant demonstrating that it could not have made the DES which caused the plaintiff's injuries. *Id.* Those defendants failing in this proof are held liable for the percentage of damages approximating their share of the relevant market. *Id.* The *Sindell* court reasoned that it was fair to shift the burden of proof on causation to the defendants in light of the fact that each defendant's market share, and therefore its share of the damages, would approximate the probability that it caused the plaintiff's injuries. *Id.*

Although we do not question the fundamental fairness of *Sindell's* shifting the burden of proof to the defendants, we conclude that the *Sindell* market share theory for apportioning damages should not be adopted in Wisconsin. The court in *Sindell* admitted that it was "not unmindful of the practical problems involved in defining the market and determining market share," but declined to use that as a reason for not adopting the market share theory. *Sindell,* 26 Cal. 3d at 613, 607 P.2d at 937. We conclude, however, that unalloyed market share theory does not constitute the most desirable course to follow in DES cases

because the theory, while conceptually attractive, is limited in practical applicability.

The primary factor which prevents us from following *Sindell* is the practical difficulty of defining and proving market share. As noted earlier, it appears many drug companies simply do not have records available from which a fact finder could determine how much DES a given defendant produced or marketed, or when and where the DES was produced and marketed. Even assuming that some drug companies have records, the fact finder still may not be able to compose an accurate assessment of the total market of which those companies were a part. There are several reasons for this: The DES market apparently was quite fluid, with companies entering and leaving the market over the years; some companies no longer exist and some that still exist may not have relevant records; and apparently there are no accurate nationwide records pertaining to the overall production and marketing of DES. We view defining the market and apportioning market share as a near impossible task if it is to be done fairly and accurately in order to approximate the probability that a defendant caused the plaintiff's injuries.[9] Further, we

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[9]We find a flaw in *Sindell's* reasoning in that it would appear to permit each defendant's market share to be increased proportionately to ensure that the plaintiff recovers her damages. *See Sindell*, 26 Cal. 3d at 612-13, 607 P.2d at 937; *see also id.* at 617, 607 P.2d at 940 (Richardson, J., dissenting). While we support the plaintiff's recovery of all her damages, requiring a defendant to pay more than its percentage of the market is directly contrary to the court's reasoning that percentage of the market approximates the probability that the defendant produced or marketed the subject DES. Furthermore, the *Sindell* court did not address itself to the problem of what is to be done with those defendants that do not have any records with which to establish their market share. Simply arbitrarily assigning the remaining percentage of the market to these defendants does not comport with probable liability. *See generally id.* and *Trends in Products Liability Litigation*, 16 Trial 82, 84 (Nov. 1980) (interview with Justice Stanley Moak, author of the *Sindell* opinion).

conclude that the waste of judicial resources which would be inherent in a second "mini-trial" to determine market share militates against its adoption by this court. We emphasize, however, that we do not totally reject the market share theory. Rather, as we explain below, we consider market share, if determinable, to be a relevant factor in apportioning liability among defendants.

We recognize that DES cases pose difficult problems. The entirely innocent plaintiffs may have been severely harmed by a drug they had no control over, and they may never know or be able to prove with certainty which drug company produced or marketed the DES taken by their mothers. The defendants are faced with possible liability for DES which they may not have produced or marketed. We conclude, however, that as between the plaintiff, who probably is not at fault, and the defendants, who may have provided the product which caused the injury, the interests of justice and fundamental fairness demand that the latter should bear the cost of injury. Accordingly, we have formulated a method of recovery for plaintiffs in DES cases in Wisconsin. We note that this method of recovery could apply in situations which are factually similar to the DES cases.

Although the defendants in this case may not have acted in concert under the concert of action theory, all participated in either gaining approval of DES for use in pregnancy or in producing or marketing DES in subsequent years. Each defendant contributed to the *risk* of injury to the public[10] and, consequently, the risk of injury to individ-

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[10]A "risk contribution" theory is proposed in Robinson, *Multiple Causation in Tort Law: Reflections on the DES Cases*, 68 Va. L. Rev. 713 (1982). Robinson argues that, from the standpoint of fairness in placing liability on the drug companies, "the critical point is the *creation of a risk* that society deems to be unreasonable, not whether anyone was injured by it." *Id.*, at 739 (emphasis in original). Because all DES drug companies produced or marketed a "de-

ual plaintiffs such as Therese Collins. Thus each defendant shares, in some measure, a degree of culpability in producing or marketing what the FDA, many scientists, and medical researchers ultimately concluded was a drug with possibly harmful side effects. Moreover, as between the injured plaintiff and the possibly responsible drug company, the drug company is in a better position to absorb the cost of the injury. The drug company can either insure itself against liability, absorb the damage award, or pass the cost along to the consuming public as a cost of doing business. We conclude that it is better to have drug companies or consumers share the cost of the injury than to place the burden solely on the innocent plaintiff. Finally, the cost of damages awards will act as an incentive for drug companies to test adequately the drugs they place on the market for general medical use.[11] This incentive is especially important in the case of mass-marketed drugs because consumers and their physicians in most instances rely upon advice given by the supplier and the scientific community and, consequently, are virtually helpless to protest themselves from serious injuries caused by deleterious drugs.

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fective" product, Robinson contends, they all contributed to the risk of injury, even though they may not have contributed to the actual injury of a given plaintiff. *Id.* at 739-40. Using this premise, Robinson argues that the plaintiff's damages should be apportioned "among all defendants that created unreasonable risks according to the magnitude of the risks they created." *Id.* at 755. Although we find Robinson's "risk contribution" theory sound to the extent it recognizes that all DES drug companies contributed in some measure to the risk of injury, we do not agree that this is a sufficient basis in itself for liability. We still require it be shown that the defendant drug company reasonably could have contributed in some way to the actual injury.

[11]In their briefs and at oral argument, the defendants contended that imposing liability on possibly innocent drug companies will discourage drug companies from producing or marketing generic drugs. It has been argued that society benefits from generic drugs because they are easier to produce and market and are, therefore, cheaper for the consumer. The defendants contend that, if liability

Practical considerations favor permitting the plaintiff to proceed, at least initially, against one defendant. One alternative would be to require the plaintiff, as in *Sindell,* to join as defendants "a substantial share" of the producers and marketers of DES. We conclude that this is unworkable because of the problems we noted earlier inherent in trying to establish the relevant market and each defendant's share of that market. Another alternative would be to require the defendant to join a "reasonable number" of possibly liable defendants. We cannot, however, define what that "reasonable number" would be because there are so many potentially liable drug companies. Moveover, either alternative would waste judicial resources by requiring an initial determination of whether the plaintiff has joined a sufficient number of defendants. We also conclude that the defendant is in a better position than the plaintiff to determine which other drug companies may share liability. We recognize that many drug companies do not have relevant records, but they, as participants in the DES market, presumably have more information or potential access to relevant information than does the plaintiff.

Thus, the plaintiff need commence suit against only one defendant and allege the following elements: that the plaintiff's mother took DES; that DES caused the plaintiff's

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were imposed on all defendants because the plaintiff cannot, due to the generic nature of DES, identify the exact producer or marketer, drug companies would seek to avoid future liability by not producing or marketing generic drugs.

While there may be some validity to the defendants' argument, we do not agree that imposing liability in this case will cause drug companies to cease producing or marketing generic drugs. We believe that this sort of liability will encourage drug companies to produce or market *safe* generic drugs. So long as drug companies properly test drugs and thereby produce or market a reasonably safe product, they need not fear liability under the rule of this case. Thus, it is not solely the generic status of the drug but the safety or efficacy of the drug, generic or otherwise, which may give rise to liability.

subsequent injuries; that the defendant produced or marketed the type of DES taken by the plaintiff's mother; and that the defendant's conduct in producing or marketing the DES constituted a breach of a legally recognized duty to the plaintiff. In the situation where the plaintiff cannot allege and prove what type of DES the mother took, as to the third element the plaintiff need only allege and prove that the defendant drug company produced or marketed the drug DES for use in preventing miscarriages during pregnancy. Applying the rules of liberal construction to complaints, we construe the plaintiff's second amended complaint as satisfying these required allegations.

At the trial of this case the plaintiff will have to prove each of these elements to the satisfaction of the trier of fact. We emphasize, however, that the plaintiff need not prove that a defendant produced or marketed the precise DES taken by the plaintiff's mother. Rather, the plaintiff need only establish by a preponderance of the evidence that a defendant produced or marketed the *type* (e.g., color, shape, markings, size, or other identifiable characteristics) of DES taken by the plaintiff's mother; the plaintiff need not allege or prove any facts related to the time or geographic distribution of the subject DES. If the plaintiff is able to prove these elements, the plaintiff may recover all damages from the one defendant. If, however, more than one defendant is joined, the plaintiff should recover from each defendant damages proportionate to the jury's assignment of liability under the comparative negligence scheme developed below.

Although we hold that it is sufficient for the plaintiff to sue only one defendant, we recognize that the plaintiff may find it preferable to sue as many defendants as can be identified as having possible liability. Simple self-interest should encourage the plaintiff to sue more than one defendant drug company. If the plaintiff cannot prove the case against the single defendant, an action against other poten-

tially liable defendants may be barred by the statute of limitations. A suit against more than one defendant, besides giving the plaintiff more opportunities to establish liability, also ensures that the plaintiff will have a better chance of actually recovering damages because there is always the possibility that the single defendant will be judgment proof.

We assume that the incentives identified above will encourage the plaintiff to sue a number of drug companies. However, in order to assure that liability in multiple defendant DES cases is equitably distributed among as many defendants as possible, any defendant may, pursuant to sec. 803.05, Stats., implead as third-party defendants other drug companies which it can allege produced or marketed the type of DES taken by the plaintiff's mother. This will permit any originally named defendant to share liability with other defendants, and will thereby result in damages being more equitably distributed among all those defendants found liable for the plaintiff's injuries. In this case, we believe it fair to direct the trial court to grant leave to the existing defendants to implead upon proper notice other possibly liable defendants. *See* sec. 803.05, Stats. After the trial court has given the defendants an opportunity to implead other defendants, Therese Collins' case may proceed to trial on two causes of action: negligence and strict products liability.

On a negligence theory, the plaintiff must prove that a defendant drug company had a duty of care and breached that duty of care when it produced or marketed DES. *See Fondell,* 85 Wis. 2d at 226-27. We note, however, that on the issue of identifying the defendant that caused the plaintiff's injury, the plaintiff need only prove by a preponderance of the evidence that an allegedly negligent defendant drug company produced or marketed the type of DES taken by the plaintiff's mother.

The plaintiff in this case may also proceed under a theory of strict products liability. In order to prevail on this theory, the plaintiff must prove (1) that the DES was defective when it left the possession or control of the drug company; (2) that it was unreasonably dangerous to the user or consumer; (3) that the defect was a cause of the plaintiff's injuries or damages; (4) that the drug company engaged in the business of producing or marketing DES or, put negatively, that this is not an isolated or infrequent transaction not related to the principal business of the drug company; and (5) that the product was one which the company expected to reach the user or consumer without substantial change in the condition it was when sold. *See Dippel v. Sciano,* 37 Wis. 2d 443, 460, 155 N.W.2d 55 (1967). We reiterate that on the issue of identifying the defendant that caused the plaintiff's injury, the plaintiff need only prove by a preponderance of the evidence that a defendant drug company produced or marketed the allegedly defective and unreasonably dangerous type of DES taken by the plaintiff's mother .

At oral argument, defendants' counsel claimed that drug companies can be held liable only on a negligence theory, not on a strict products liability theory. Support for this proposition is found in comment k to sec. 402A of the Restatement (Second) of Torts (1965). Comment k identifies drugs as unavoidably unsafe products because "in the present state of human knowledge, [they] are quite incapable of being made safe for their intended and ordinary use." Under the premise that properly prepared drugs accompanied by proper directions and warnings are, therefore, not *unreasonably* dangerous, the comment concludes that the sellers of drug products should not be held strictly liable "for unfortunate consequences attending their use." The comment advances as a policy justification for this rule the necessity for some drugs to be put on the market without adequate testing because of the urgent need for treat-

ment of a serious health hazard. The comment, however, recognizes that such preparation and marketing requires that a proper warning be given if the provider is not to be held strictly liable.

Although we adopted sec. 402A in *Dippel v. Sciano, supra,* we specifically declined to accept or reject any of the comments. *Dippel,* 37 Wis. 2d at 459. We have not adopted comment k to sec. 402A, and we decline to do so in this case. We conclude that the rule embodied in comment k is too restrictive and, therefore, not commensurate with strict products liability law in Wisconsin.

Drug companies, like other sellers or manufacturers, have a duty to produce and market reasonably safe products. We recognize that in some exigent circumstances it may be necessary to place a drug on the market before adequate testing can be done. Insofar as these circumstances exist, we agree with the comment that strict liability should not be imposed. However, we find no exigent circumstances which would excuse DES producers or marketers from adequately testing DES before it was placed on the market. Although there was a societal interest in preventing miscarriages in pregnancy, alternative treatment was available, and the problem did not approach epidemic proportions. Even assuming there were exigent circumstances in 1947 necessitating the use of DES in pregnancy without adequate testing, an additional ten years had elapsed by the time the plaintiff's mother took DES. Thus, it would appear the drug companies had sufficient time to test DES thoroughly even if the original need to place it on the market foreclosed adequate testing at that time. Accordingly, we hold that DES producers or marketers may be held strictly liable if the plaintiff establishes the five elements specified earlier.

Once the plaintiff has proven a *prima facie* case under either cause of action, the burden of proof shifts to the

defendant to prove by a preponderance of the evidence that it did not produce or market the subject DES either during the time period the plaintiff was exposed to DES or in the relevant geographical market area in which the plaintiff's mother acquired the DES. In utilizing these defenses, the defendant must establish that the DES it produced or marketed could not have reached the plaintiff's mother. We conclude that it is appropriate to shift the burden of proof on time and geographic distribution to the defendant drug companies because they will have better access to relevant records than the plaintiff. Further, if relevant records do not exist, we believe that the equities of DES cases favor placing the consequences on the defendants.

We believe that this procedure will result in a pool of defendants which it can reasonably be assumed could have caused the plaintiff's injuries. We note in this regard that, in cases where the plaintiff's mother took DES over a period of time and had the prescription refilled, it is possible that DES from several drug companies may have contributed to the plaintiff's injuries. This still could mean that some of the remaining defendants may be innocent, but we accept this as the price the defendants, and perhaps ultimately society, must pay to provide the plaintiff an adequate remedy under the law.[12]

Regardless of which causes of action the plaintiff in this case proceeds upon, the jury will have to apply Wisconsin's

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[12]The defendants argue that the plaintiff's remedy in this type of case should be fashioned by the legislature. The defendants cite as examples black lung legislation and the proposed fund for victims of asbestos-caused diseases. We disagree with this argument. It is the function of this court to modify the existing common law if that becomes necessary to promote justice under the law.

comparative negligence statute, sec. 895.045, Stats.[13] Under Wisconsin's comparative negligence doctrine, the amount of liability—and hence, the proportion of the total damages —is determined in proportion to the percentage of causal negligence attributable to each defendant. *Bielski,* 16 Wis. 2d at 6. Comparative negligence will be determined by the trier of fact both under a negligence theory, *see generally Bielski v. Schulze, supra,* and under a strict products liability theory because of our "negligence per se" formulation of liability, *see Dippel,* 37 Wis. 2d at 460-62; *Greiten v. La Dow,* 70 Wis. 2d 589, 600, 235 N.W.2d 677 (1975).

After carefully weighing the alternatives, we conclude that the application of comparative negligence in DES cases provides the most equitable means to assign liability and apportion damages among the liable defendants. As this court has stated:

". . . The apportionment of negligence is the peculiar province of the jury. The degree of negligence attributable to a party is not to be measured by the character thereof nor by the number of respects in which he is found to have been at fault. It is the conduct of the parties considered as a whole which should control. In other words, once it has been established that each has been negligent, it is then the jury's function to weigh their respective contributions to the result, which will, regardless of the nature of their acts or omissions, determine which made the larger contribution and to what extent it exceeds or is less than that of the other."

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[13]Section 895.045, Stats., provides:

"Contributory negligence. Contributory negligence shall not bar recovery in an action by any person or his legal representative to recover damages for negligence resulting in death or in injury to person or property, if such negligence was not greater than the negligence of the person against whom recovery is sought, but any damages allowed shall be diminished in the proportion to the amount of negligence attributable to the person recovering."

Taylor v. Western Casualty & Surety Co., 270 Wis. 408, 411-12, 71 N.W.2d 363 (1955). In discussing the general theory of comparative negligence, we have recognized that it "is an equitable doctrine based on natural justice." *Bielski*, 16 Wis. 2d at 7.

We believe that comparative negligence is a flexible doctrine which will permit the jury in DES cases equitably to apportion liability among the defendants that have been unable to exculpate themselves. In assigning a percentage of liability to each defendant, the jury may consider factors which include, but are not limited to, the following: whether the drug company conducted tests on DES for safety and efficacy in use for pregnancies; to what degree the company took a role in gaining FDA approval of DES for use in pregnancies; whether the company had a small or large market share in the relevant area; whether the company took the lead or merely followed the lead of others in producing or marketing DES; whether the company issued warnings about the dangers of DES; whether the company produced or marketed DES after it knew or should have known of the possible hazards DES presented to the public; and whether the company took any affirmative steps to reduce the risk of injury to the public. This list of factors is not exclusive, and the trial court may in its discretion permit the jury to consider other factors relevant to apportioning liability. Although the allocation of liability will present a difficult task for juries, we conclude that it is the best method to ensure that liability will be assigned equitably accorded to relative fault.[14]

---

[14]We note that in multiple tortfeasor cases the negligence of the plaintiff is compared to the negligence of each defendant. *Wisconsin Natural Gas v. Ford, Bacon & Davis Construction*, 96 Wis. 2d 314, 327, 291 N.W.2d 825 (1980). We cannot conceive, however, of any situation where the DES plaintiff, who was a fetus at the time the DES was taken, could be attributed with anything but zero percent negligence. Consequently, we presume that in all DES cases 100 percent of the liability will be apportioned only among the defendants.

We recognize that under Wisconsin's strict products liability law the sale of a defective and unreasonably dangerous product constitutes, assuming all other elements are proven, negligence per se. *Greiten*, 70 Wis. 2d at 600. The plaintiff is relieved of proving specific acts of negligence on the part of the defendant, *Dippel*, 37 Wis. 2d at 460, because it is the nature of the product, not the degree of care, which gives rise to liability, *Greiten*, 70 Wis. 2d at 604. Therefore, the preceding factors need not be used to establish negligence because negligence per se can be proven through the five elements specified in our discussion concerning strict products liability in DES cases. However, the factors may properly be used to apportion liability among the defendants the jury determines to be strictly liable for the DES plaintiff's injuries.

A final element of damages merits discussion. The plaintiff in this case has sought punitive damages because the defendants allegedly recklessly disregarded the plaintiff's rights by their conduct associated with the production and marketing of DES. In order to recover punitive damages in Wisconsin, the injured party must show a wanton, willful, or reckless indifference to or disregard for the rights of others on the part of the wrongdoer. *Fahrenberg v. Tengel*, 96 Wis. 2d 211, 221, 291 N.W. 2d 516 (1980). Similarly, punitive damages may be awarded in products liability cases where it is shown that the defendant wantonly, willfully, or recklessly disregards the plaintiff's rights by selling a defective and unreasonably dangerous product. *Wangen v. Ford Motor Co.*, 97 Wis. 2d 260, 308, 294 N.W.2d 437 (1980).

Punitive damages are designed to punish a wrongdoer and to serve as a deterrent. *Mid-Continent Refrigerator Co. v. Straka*, 47 Wis. 2d 739, 746, 173 N.W.2d 28 (1970). The concept of punitive damages embodies a rule for indi-

vidualized punishment of a wrongdoer whose conduct toward the plaintiff is particularly outrageous. Implicit in this concept is the notion that, where punishment is to be exacted, it must be certain that the wrongdoer being punished because of his conduct actually caused the plaintiff's injuries. Under this rule Therese Collins, who has sued multiple defendants and has represented that she cannot prove which defendant actually caused her injuries, may not recover punitive damages.

In her second amended complaint, the plaintiff alleged that the defendants had "intentionally, deceitfully, fraudulently, recklessly, or innocently" misrepresented that DES was safe and efficacious for use in preventing miscarriages during pregnancy. The plaintiff further alleged that Dr. Wendt, Mrs. Collins' physician, had relied upon these misrepresentations when prescribing DES for Mrs. Collins. However, in an affidavit submitted by the defendants in conjunction with their motions for summary judgment, Dr. Wendt stated that he relied only on general medical information and "did not use [DES] because of anything that any drug company had told me, and as a matter of fact, no drug company had called on me in respect to using this drug." Dr. Wendt confirmed this fact in his deposition taken July 22, 1981. The plaintiff did not submit an affidavit or any other evidence controverting this fact. Even assuming that the defendants made misrepresentations concerning DES, since there was no reliance on those misrepresentations, there can be no recovery under this cause of action. *See* W. Prosser, *Handbook of The Law of Torts*, sec. 108 (4th ed. 1971); *Household Finance Corp. v. Christian*, 8 Wis. 2d 53, 55-56, 98 N.W.2d 390 (1959).

We have stated that:

". . . Pursuant to sec. 802.08(2), Stats., summary judgment shall be granted 'if the pleadings, depositions, answers to interrogatories, and admissions on file, together

with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.' "

Maynard v. Port Publications, Inc., 98 Wis. 2d 555, 558, 297 N.W.2d 500 (1980). Under this standard, the trial court was obliged to grant summary judgment in favor of the defendants on the plaintiff's third cause of action as set forth in her second amended complaint. Accordingly, we affirm the trial court's granting of summary judgment in sofar as it relates to this cause of action.

In deciding a motion for summary judgment, the initial question is whether the complaint states a claim upon which relief can be granted. *See Prah v. Maretti,* 108 Wis. 2d 223, 228, 321 N.W.2d 182 (1982). The complaint should be dismissed as legally insufficient only if " 'it is quite clear that under no circumstances can the plaintiff recover.' " *Id.* at 229 (citation omitted). We conclude that the plaintiff has stated a claim for which relief can be granted. Accordingly, we find that the trial court erred in granting summary judgment on the general issue of liability. We reverse the trial court's judgment and remand the case for trial on the causes of action approved in this opinion.

Several defendants have filed affidavits and other materials in support of their separate motions for summary judgment. The motions are based upon these defendants' contentions that for one reason or another they could not have produced or marketed the DES taken by the plaintiff's mother. In granting the defendants' joint motion for summary judgment, the trial court did not address the other individual motions. We determine that the trial court should, upon remand, consider these motions and decide whether summary judgment is appropriate based upon the holding of this opinion.

The remaining issue is whether the trial court erred in denying the plaintiff's motion to amend her second amended complaint. The trial court concluded that the plaintiff had not alleged any new facts, nor had the plaintiff shown sufficient reasons for permitting an amendment of her second amended complaint. Allowing a party to amend pleadings is within the trial court's discretion, *Gustavson v. O'Brien*, 87 Wis. 2d 193, 205, 274 N.W.2d 627 (1979), and will not be reversed unless there has been a manifest abuse of discretion, *Celmer v. Quarberg*, 56 Wis. 2d 581, 592, 203 N.W. 2d 45 (1973). The trial court carefully stated the grounds for its exercise of discretion and based its decision on factors we consider relevant to the determination. Accordingly, we find no manifest abuse of discretion in the trial court's denial of the plaintiff's motion to amend, and, therefore, we affirm the trial court's order.

By the Court.—Judgment reversed in part, affirmed in part, and cause remanded for trial and further proceedings consistent with this opinion; order affirmed.

SHIRLEY S. ABRAHAMSON, J. (concurring). I agree with the majority's decision that the plaintiff's complaint states a cause of action. I am persuaded that a cause of action should be recognized on a risk contribution theory. I write separately for two reasons.

First, I believe the majority unnecessarily confuses the issue of apportionment of damages by saying that the "jury will have to apply Wisconsin's comparative negligence doctrine, sec. 895.045, Stats.," *supra*, p. 198. Because plaintiff need not prove that the defendant's negligence or product caused her damage in order for the defendant to be liable, sec. 895.045 is not really applicable here except by analogy. The doctrine of comparative negligence encompassed in "sec. 895.045, Stats., has been construed from its beginning to apply only to *causal* negligence. . . ." *Love-*

see v. Allied Devel. Corp., 45 Wis. 2d 340, 343, 172 N.W.2d 196 (1970) (emphasis added). See also *City of Franklin v. Badger Ford Truck Sales*, 58 Wis. 2d 641, 653-55, 207 N.W.2d 866 (1973) (products liability case). I believe the majority tries to fit apportionment of damages within the comparative negligence statute, even though the causal element is not an issue in this kind of case, because it wishes to use two concepts present in the doctrine of comparative negligence: jury apportionment of damages and jury consideration of the kind and character of the defendants' conduct. *Lovesee, supra*, at 345.

Second, although I may not necessarily disagree with the discussion, I do not join the dictum concerning punitive damages. This issue is unnecessary for disposition of the case and was not briefed by the parties.

Appendix B

SUPREME COURT OF WISCONSIN

Case No. 82-1844

Therese Marie Collins, now known
as Therese Marie Gastrow,
Plaintiff-Appellant,

vs.

Eli Lilly and Company; Rexall Drug Company;
E. R. Squibb and Sons, Inc.; Abbott Laboratories;
Boyle and Company; Cooper Laboratories, Inc.
(formerly Brewer and Company, Inc., and
Sherman Laboratories): Vale Chemical Company; and
Upjohn Company; Cole Pharmacal Company; McNeil
Laboratories, Inc.; Carnrick Laboratories, a division
of G. W. Carnrick Company; Emons Industries, Inc.
(formerly Amfre-Grant and Grant Chemical Company);
E. S. Miller Laboratories, a division of Smith, Miller &
Patch Products, Premo Pharmaceutical Laboratories, Inc.;
Kremers-Urban Company; Merck, Harp & Dohme; and
William A. Webster Company; and others,
Defendants-Respondents

[Filed Jan. 24, 1984]

MOTION FOR RECONSIDERATION

The defendants-appellees respectfully move the Court, pursuant to Rules 804.14 and 809.64, to reconsider its decision filed January 4, 1984. For the reasons stated in the accompanying memorandum, defendants submit that the decision should be modified in the following respects:

1. The Court's decision that, except in exigent circumstances, the principle of Comment k to Section 402A of the Restatement of Torts (Second) regarding unavoidably unsafe products does not apply to cases involving prescription drugs, should be withdrawn as premature. Defendants

submit that this is an important question of law, with broad implications for many cases, and that the Court should have the benefit of a full record, briefs and argument. See Section I of Defendants' Memorandum. The importance of a full hearing is emphasized by the fact that important public policy concerns are implicated by the Court's decision and the fact that its decision is inconsistent with the great weight of authority elsewhere. See Section II of Defendants' Memorandum.

2. While defendants do not agree with the risk contribution rule adopted by the Court, defendants submit that the rule should be refined in two important respects if it is to have any opportunity to fulfill its objectives. First, the responsibility to prove the extent or degree of a pharmaceutical company's contribution to the risk of injury to the public allegedly posed by DES should be specifically assigned to the plaintiff. Second, the Court should specify that the liability of any defendant shall be limited to that proportion of plaintiff's total damages which represents that company's contribution to the general risk, compared to the contributions of all companies toward the general risk. Further, defendants submit that the partial list of factors to be considered by the jury and set forth in the court's opinion should be withdrawn, pending litigation and development of a record on the issues of alleged negligence. See Memorandum, Section III.

3. Finally, defendants raise and preserve for possible further appeal their constitutional objections to the Court's risk contribution rule. See Memorandum, Section IV.

Respectfully submitted,

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Appendix C

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State of Wisconsin

Madison, February 27, 1984

To

Gerald J. Bloch, Milwaukee
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Laura D. Stith, Kansas City, MO
Carl N. Otjen, Milwaukee
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Irving W. Zirbel, Milwaukee
Edmund W. Powell, Milwaukee
Robert A. DuPuy, Milwaukee
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John A. Kluwin, Milwaukee
Hugh Moore, Chicago, IL

The Court today announced an order in your case as follows:

Therese Marie Collins, n/k/a Therese Marie Gastrow v. Eli Lilly Company, et al, #82-1844.

The Court having considered the Motion for Reconsideration filed herein and the response thereto,

IT IS ORDERED that the Motion for Reconsideration is denied with costs.

MARILYN L. GRAVES
Clerk of Supreme Court

Supreme Court, U.S.
FILED
JUN 18 1984
ALEXANDER L. STEVAS
CLERK

83-1932

No. ~~83-192~~2

IN THE

Supreme Court of the United States

OCTOBER TERM 1983

E.R. SQUIBB & SONS, INC.,

Petitioner,

vs.

THERESE MARIE COLLINS, et al.,

Respondents.

On Petition for Writ of Certiorari to the Supreme Court of Wisconsin

JOINT MEMORANDUM SUPPORTING CERTIORARI

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OCTOBER TERM 1983

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Petitioner,

vs.

THERESE MARIE COLLINS, et al.,

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On Petition for Writ of Certiorari to the Supreme Court of Wisconsin

JOINT MEMORANDUM SUPPORTING CERTIORARI

Respondents Abbott Laboratories, Boyle & Company, Carnrick Laboratories, Inc., Cole Pharmacal Company, Cooper Laboratories, Inc., Emons Industries, Inc., Merck, Sharp & Dohme, E.S. Miller Laboratories, The Upjohn Company, and Vale Chemical Company, all of whom were defendants in the trial court below, support the Petition for Writ of Certiorari of E.R. Squibb & Sons, Inc., and

submit that the Writ should issue to the Supreme Court of Wisconsin in this cause for the reasons stated in that Petition.

Respectfully submitted,

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June 18, 1984

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FILED
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CLERK

(3)

No. 83-1932

In the Supreme Court of the United States

OCTOBER TERM, 1983

E. R. SQUIBB & SONS, INC.,

Petitioner,

vs.

THERESE MARIE COLLINS, et al.,

Respondents.

On Petition For A Writ Of Certiorari
To The Supreme Court Of Wisconsin

BRIEF OF RESPONDENT THERESE MARIE COLLINS IN OPPOSITION

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146 pp

QUESTIONS PRESENTED

1. Whether a state's modification of its tort law to permit a rebuttable presumption of causation-in-fact under certain circumstances in an unusual class of personal injury cases violates the Due Process or Equal Protection Clauses of the Fourteenth Amendment to the United States Constitution?

2. Whether a state-created rebuttable presumption of causation-in-fact in personal injury cases involving harm caused by the pregnancy drug DES violates the Supremacy Clause or the Interstate Commerce Clause of the United States Constitution?

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In the
Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-1932

E. R. SQUIBB & SONS, INC.,

Petitioner,

vs.

THERESE MARIE COLLINS, et al.,

Respondents.

On Petition For A Writ Of Certiorari
To The Supreme Court Of Wisconsin

BRIEF OF RESPONDENT THERESE MARIE COLLINS IN OPPOSITION

OPINION BELOW

The opinion of the Wisconsin Supreme Court is reported at 116 Wis.2d 166, 342 N.W.2d 37 (1984). The opinion is reproduced at pages 1-32 of the Appendix to the Petition ("Pet. App.-1-32").

STATEMENT OF THE CASE

We do not accept the statement of the case contained in the Petition. It is more appropriately categorized as an argument than as a statement of the case. For this reason, we present our own statement of the case.

Therese Marie Collins contracted cancer which necessitated the removal of her uterus, part of her vagina and a number of lymph nodes. As a result of the radical cancer surgery necessary to save her life, her bladder has ceased functioning. Pet. App.-2-3.

Ms. Collins filed suit against Petitioner and 16 other producers of the drug DES—the drug her mother took during pregnancy, and which she alleged resulted in the cancer from which Ms. Collins suffers. Before the trial court, Ms. Collins asserted that even though she could not pinpoint which drug company produced the pills her mother had taken, the trial court should modify the cause-in-fact requirement in Wisconsin in order to permit her to proceed with her case. The trial court refused, saying that such arguments were more appropriately addressed to the state supreme court. The Wisconsin Supreme Court undertook review, bypassing the intermediate appellate court.

The issue confronting the Wisconsin Supreme Court in the *Collins* case develops from the unusual circumstances that attend injury from DES consumption. The consumption of DES that gives rise to the injury occurs when the victim's *mother* ingests the drug while the mother is pregnant with the victim. The injurious consequences of DES consumption manifest themselves 10 to 20 years after the drug is consumed. This time gap makes it virtually impossible for most DES daughters to identify the manufacturer of the DES pills taken by their mothers.

Before the Wisconsin Supreme Court, Ms. Collins urged various modifications of the traditional cause-in-fact requirement, including market share liability among the defendants as announced in *Sindell* v. *Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, *cert. denied*, 449 U.S. 912 (1980). Petitioner and the other defendant drug companies argued against any such modifications. The federal constitutional argument made by Petitioner and the other defendant drug companies for opposing the modification to the cause-in-fact rule was entirely contained in a two-sentence footnote in a 65-page brief before the state supreme court. The footnote is reproduced in full in Appendix A to this brief.

After examining the drug companies' arguments and the various modifications urged by Ms. Collins, the Wisconsin Supreme Court adopted its own rule concerning proof of causation-in-fact in DES situations, which rule, the court noted, also "could apply in situations which are factually similar to the DES cases." Pet. App.-18. The state supreme court's formulation created a rebuttable presumption of causation that attaches to any drug company defendant who produced DES. The presumption is based on the fact that each defendant who produced DES contributed to the risk of public injury, and, consequently, to the risk of individual injury that gave rise to the lawsuit. A defendant may rebut the presumption by showing that it was not the company that made the DES pills giving rise to the injury because it did not produce DES during the relevant time period, or did not market its DES in the relevant geographic area or in the physical form identified by the plaintiff. Pet. App.-18, 24-25. This allocation of proof in connection with the presumption is made because it is the defendant drug company, rather than the plaintiff, who has best access to knowledge of those facts.

Pet. App.-20. The alleged DES victim, however, still retains the burden of showing her injury in fact *was* caused by DES. The alternative to modifying traditional cause-in-fact allocations would be to deny the DES plaintiff any recovery whatever, where she cannot pinpoint the precise manufacturer of the DES pills which caused her injury.

The court's decision does not discuss the federal constitutional objections Petitioner mentioned in the two-sentence footnote contained in its state appellate brief. Petitioner and the other defendant drug companies sought reconsideration of the Wisconsin Supreme Court's decision. Pet. App.-33. The Wisconsin Supreme Court denied the motion for reconsideration without opinion. The case was remanded and is now proceeding in the state trial court. Petitioner has filed a summary judgment motion based on its assertion that its DES pills during the relevant time period were pink and did not match the description given by Ms. Collins' mother. *See* Pet. at 6. This summary judgment motion and that of other individual defendants who claim they can prove under the *Collins* decision that they did not produce the pills that caused Ms. Collins' injury are scheduled to be heard on July 9, 1984. Trial is scheduled for March 5, 1985.

REASONS FOR DENYING THE WRIT

Petitioner is the only one of 17 defendant drug companies to petition this Court to review the *Collins* decision of the Wisconsin Supreme Court, a decision which neither discusses nor states any principle of federal constitutional law. The *Collins* decision enunciates solely the policy of the state of Wisconsin. It is a policy with which Petitioner may disagree, but to which several of Wisconsin's sister states subscribe. *See Abel* v. *Eli Lilly & Co.*, 418 Mich. 311, 343 N.W.2d 164 (1984); *Sindell* v. *Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, *cert. denied*, 449 U.S. 912 (1980); *McElhaney* v. *Eli Lilly & Co.*, 564 F. Supp. 265 (D. S.D. 1983); *Bichler* v. *Eli Lilly & Co.*, 55 N.Y.2d 571, 436 N.E. 2d 182 (1982). None of these decisions has discussed any federal constitutional dimension in their adaptation of the common law to meet the unusual issues presented by DES and similar cases. Other courts (all but one of them federal courts applying state law) have made different policy judgments and declined to adapt the local common law in this context, but none has done so on federal constitutional grounds. *See Morton* v. *Abbott Laboratories*, 538 F. Supp. 593 (M.D. Fla. 1982); *Ryan* v. *Eli Lilly & Co.*, 514 F. Supp. 1004 (D. S.C. 1981); *Payton* v. *Abbott Laboratories*, 512 F. Supp. 1031 (D. Mass. 1981); *Gray* v. *United States*, 445 F. Supp. 337 (S.D. Tex. 1978); *Lyons* v. *Premo Pharmaceutical Labs, Inc.*, 170 N.J. Super. 183, 406 A.2d 185 (1979).

Further, numerous commentators have analyzed the issues attending DES litigation, but none has discerned federal constitutional problems with the types of adaptation

of common law that the *Collins* decision undertook.[1] The articles containing the commentators' analyses are listed in Appendix B to this Brief in Opposition. In short, then, neither courts nor commentators have found the approaches to causation involved in this and other DES cases to be constitutionally suspect.

Petitioner's position—that the *Collins* court's adaptation of common law is constitutionally suspect—is grounded in an expanded notion of the Constitution's reach, a notion that would reorder federal-state relations. In essence, Petitioner asks that, under the guise of interpreting the federal Constitution, this Court should not tolerate variances in state approaches to tort law. Because this is not a case where existing pronouncements of federal law must be reconciled—indeed, federal issues have never been addressed by the courts in the context of DES litigation—this Court should not undertake the review requested here.

I.

THE COLLINS DECISION DOES NOT DEPRIVE PETITIONER OF DUE PROCESS OF LAW.

The Fourteenth Amendment provides that "[n]o state shall . . . deprive any person of life, liberty, or property, without due process of law." This provision has been interpreted to provide both procedural and substantive safeguards.

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[1] The one commentator who discusses a federal constitutional issue in the context of DES litigation raises the question in connection with awards of punitive damages, an issue not present here. Comment, *Punitive Damages in DES Market Share Litigation*, 23 Santa Clara L. Rev. 185 (1983). Indeed, the Wisconsin Supreme Court in *Collins* specifically disallowed punitive damages in DES cases. Pet. App.-28-29.

A. The Collins Decision Does Not Deprive Petitioner Of Procedural Due Process.

Petitioner argues that the *Collins* decision creates a rule of evidence relating to causation that deprives it of procedural due process. Specifically, Petitioner claims that drug manufacturers who did not produce the DES tablets actually taken by Ms. Collins' mother may be improperly forced to share in the monetary liability of the company or companies that did produce the tablets.

Procedural due process is a flexible principle that must be adapted to each situation in order to balance the interests at stake. Although the due-process right to a hearing is generally found to embrace the right to present evidence, a state has considerable power to make or change rules that govern the introduction of evidence at trial to prove a particular issue. *Luria* v. *United States,* 231 U.S. 9 (1913). In fact, it is "evident that a right to have one's controversies determined by existing rules of evidence is not a vested right." 231 U.S. at 26.

1. The Collins Decision Does Not Create A Conclusive Presumption Of Causation.

A conclusive presumption is one which states a rule of substantive law. In contrast, a rebuttable presumption is a form of evidence that may be accepted when there is no other evidence to uphold the contention it supports, and may be rejected if it is overcome by other evidence. 9 J. Wigmore, *Evidence* §§2491, 2492 (3d ed. 1940).

Petitioner argues that the effect of the decision in *Collins* is to create a conclusive presumption that requires the trier of fact to find causation from the mere manufacture of DES. This characterization of the *Collins* ruling is inaccurate. The *Collins* formulation simply shifts the burden

of proof to the defendant drug manufacturers when the plaintiff cannot pinpoint which company manufactured the DES pills that her mother ingested.

There is, therefore, no substantive change in the law, but only a procedural change from which Petitioner has no constitutional right to be protected. *Easterling Lumber Co.* v. *Pierce,* 235 U.S. 380 (1914). Under the *Collins* rule, each defendant drug manufacturer may demonstrate that it did not make the pills that caused the plaintiff's injuries. Because each defendant is allowed to introduce such evidence, the decision can, at most, be interpreted as creating a rebuttable presumption of causation-in-fact. Indeed, the *Collins* decision goes to some length to detail what the rebutting evidence may be, including proof that the pills taken do not match the physical description of the defendant drug company's pills, that the company did not manufacture DES at the relevant time, or that it did not market DES in the relevant geographic area. Pet. App.-21, 24-25. Petitioner is simply incorrect when it states that the Wisconsin Supreme Court's decision offers no meaningful opportunity for a defendant drug manufacturer to exculpate itself.

2. As A Rebuttable Presumption Of Causation-In-Fact, The Collins Decision Does Not Deprive Petitioner Of Procedural Due Process.

In civil cases, procedural due process requires that rebuttable presumptions and allocations of the burden of proof satisfy the standard of "rationality." In a case involving statutory presumptions in a context markedly similar to the present one, this Court set out a standard for testing presumptions involving economic regulation of civil matters. *Usery* v. *Turner Elkhorn Mining Co.*, 428 U.S. 1 (1976). The *Turner* case involved a Fifth Amendment due-process

challenge to certain evidentiary rules contained in the federal statute which provides a remedy to coal workers suffering from pneumonociosis (black lung disease). Under the statute, a coal mine operator is liable for death or total disability due to pneumonociosis contracted during employment in the operator's mine. Two coal mine operators challenged certain evidentiary rules designed to establish the element of causation. Despite due-process arguments almost identical to those advanced by Petitioner in this case, the *Turner* Court upheld the constitutionality of all the evidentiary presumptions in the federal statute.[2]

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[2] The major similarities between the *Turner* rebuttable presumption and the presumption as to causation in *Collins* are as follows:

(a) In *Turner*, the plaintiff coal miner or his survivors could shift the burden of proof for causation to the defendant coal mine operator by showing employment in the coal mines for a certain number of years. Under the *Collins* rule, a plaintiff DES daughter can shift the burden of proof for causation to the defendant drug companies by showing that she has joined in the action one or more potential manufacturers of the DES which her mother might have taken, with the opportunity available to that defendant to implead any additional such manufacturers.

(b) Like the defendants in *Turner*, the defendants in *Collins* have the opportunity to introduce evidence to show the lack of causation.

(c) Both the statute in *Turner* and the rule of *Collins* are cost-spreading devices which operate with less than perfect mathematical accuracy in individual cases. The statute in *Turner* could potentially hold a coal mine operator liable for pneumonociosis that was not contracted in his mines. Under the terms of the statute, a coal mine operator who cannot disprove causation can be held liable for death or disability benefits of a coal miner who contracted the disease while employed by a former employer or who never actually contracted the disease at all. Under the rule of *Collins*, a defendant drug man-

(footnote continued)

The Court in *Turner* articulated the standard it applied to determine whether the presumption was valid. The Court stated that "it is only essential that there shall be some rational connection between the fact proved and the ultimate facts presumed, and that the inference of one fact from proof of another shall not be so unreasonable as to be a purely arbitrary mandate." 428 U.S. at 28.

In *Collins*, the shifting of the burden of proof for causation is triggered by proof that (a) DES ingested by her mother caused the plaintiff's injuries, and (b) the plaintiff has joined one or more of the manufacturers of DES, which her mother ingested, with the manufacturers so joined entitled to implead any manufacturers who should have been joined but were not. There must be at least "some

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(footnote continued)

ufacturer who fails to show a lack of causation can be held liable for a proportion of the judgment even though it may not have manufactured the particular DES that was ingested by the plaintiff's mother.

The following are among the due process arguments that are common to Petitioner in this case and the defendants in *Turner*:

(a) The presumptions and limitations on rebuttal evidence unconstitutionally impair the defendant's ability to defend against the claims.

(b) The rules operate in an arbitrary and irrational manner by holding particular defendants liable for injuries they may not have actually caused.

(c) The rules will unfairly burden certain members of the industry.

(d) The rules create an improper method of cost spreading.

(e) The facts triggering the operation of presumptions are arbitrary (*i.e.*, in *Turner*, a 10 or 15-year period of working in the mines; in this case, sales of DES in the relevant geographic area during the relevant time period).

rational connection'' between proof that those manufacturers have been joined and the presumption that one of the defendants so joined is actually responsible for the plaintiff's injuries, and that all are responsible for the risk to the public occasioned by the marketing of DES.

In light of this Court's holding in *Turner*, the *Collins* presumption operates in a rational way. A presumption that one of several defendants caused an injury is not any more ''arbitrary'' or ''irrational'' than a presumption that a miner died due to pneumonociosis (based on proof that he worked in the mines for ten years and dies of a ''respirable disease''). In fact, the possibility of error under the *Collins* rule is actually smaller than that under the statute in *Turner*. Because the defendants in *Collins* are free to implead as many other manufacturers as they like, the possibility that none of the defendants before the court caused the plaintiff's injury can virtually be eliminated. Each of the defendants, of course, is responsible for creating the public risk that is manifest in the individual plaintiff: the production and marketing of a harmful drug having a chemical constituency identical to that of each of its competitors' pills.

The *Turner* case does not require that the rules of law relating to causation match liability and actual responsibility for injury with mathematical accuracy. Responding to the argument that the retroactive application of the statute creates the possibility that a coal mine operator may be held liable for injuries that he did not actually cause, the Court in *Turner* stated that ''the imposition of liability for effects and disabilities bred in the past is justified as a rational measure to spread the costs of the employee's disabilities to those who have profited from the fruits of their labor—the operators and the coal consumers. . . .'' 428 U.S. at 18. The *Collins* decision does not prevent Peti-

tioner or any other possible defendant from presenting its evidence that *its* DES pills were not the ones ingested by Therese Collins' mother. Under the *Turner* analysis, this is more than is necessary to sustain the *Collins* presumption as rational, and therefore not violative of Petitioner's procedural due process rights.

B. The Collins Decision Does Not Deprive Petitioner Of Substantive Due Process.

Under the presumption established in *Collins*, each defendant who fails to demonstrate that it did not make the pills that caused the plaintiff's injuries is held liable for a portion of the judgment on a comparative negligence basis. Petitioner claims that this presumption and apportionment of judgment among the defendants is arbitrary and irrational and, as a result, deprives it of substantive due process. This is incorrect.

1. The Collins Decision Comes Before This Court With A Presumption Of Constitutionality For Purposes Of Due-Process Review.

The *Collins* decision creates a rule of law affecting the economic and social welfare of the citizenry of Wisconsin. The rule is designed to provide a remedy for injuries suffered by innocent persons caused by a harmful product, and to spread the costs of such injuries among the manufacturers who profited from its production.

When a rule of law which adjusts the benefits and burdens of economic life for social welfare reasons is challenged before this Court, the rule is presumed to be constitutional. The burden is on the one complaining to establish that the rule operates in an arbitrary and irrational manner. *Usery* v. *Turner Elkhorn Mining Company*, 428

U.S. 1 (1976); *Ferguson* v. *Skrupa*, 372 U.S. 726 (1962); *Williamson* v. *Lee Optical Co.*, 348 U.S. 483, 487-88 (1955); *United States* v. *Carolene Products Co.*, 304 U.S. 144, 148 (1938).

2. The Collins Decision Rests Upon A Rational Basis And Is Consistent With Historic State Tort Law Approaches To Causation Problems.

The standard for testing the due-process constitutionality of a rule of law regulating economic relationships and social welfare was specified in *United States* v. *Carolene Products Co.*, 304 U.S. 144 (1938). In that case, Justice Stone stated:

> "Regulatory legislation affecting ordinary commercial transactions is not to be pronounced unconstitutional unless in light of the facts made known and generally assumed it is of such a character as to preclude the assumption that it rests upon some *rational basis* within the knowledge and experience of the legislators." 304 U.S. at 152 (emphasis added).

The Wisconsin Supreme Court's thorough discussion of the problem it faced in *Collins* and its resolution of that problem, makes it clear that there is a rational basis for the rebuttable presumption established in the decision. Specifically, the problem arises from the DES plaintiff's inability to identify which drug company or companies manufactured the actual DES pills ingested by the plaintiff's mother. The Wisconsin Supreme Court resolves the dilemma by putting the burden on the defendant drug company to demonstrate that it did not market DES at the time or in the geographic market or in the form in which the drug was ingested. This preserves rather than eliminates the defendant drug company's existing defenses, and places the burden to overcome the presumption in the

hands of the party most likely to have information as to whether it may have contributed to the risk—the manufacturer of the drug. It is in fact the manufacturer even more so than the doctor prescribing DES (the only logical alternative defendant a plaintiff could turn to if she cannot join the manufacturer) who has the best access to information about its own marketing history.

The Wisconsin Supreme Court decided that division of liability by comparative negligence among all manufacturing drug companies who put the public at risk was the best method of compensating the innocent victims of DES, while fairly protecting the property interests of the defendant drug manufacturers. In so concluding, the state court recognized that the facts before it made it *impossible* to create a rule that exactly matched liability with actual responsibility for injury. At the extremes, the court was faced with either denying relief to DES daughters who cannot identify the manufacturer of the DES pills their mothers ingested or holding undiluted joint and several liability against the drug manufacturers. Refusing to accept either extreme, the Wisconsin Supreme Court fashioned a rule of law that militates the inequities of both extremes. The court adopted a rule of law that will allow damages to be apportioned according to the comparative culpability among the defendants whose actions put the public health at risk, and who cannot demonstrate that they did not cause the plaintiff's injuries. Surely it is *not* irrational for a court to provide a remedy that protects the interests of both the plaintiff and the defendants in a tort case.

The Wisconsin Supreme Court's resolution is consistent with time-honored allocations of proof and presumption in state tort law throughout this country. Perhaps the clearest analogy in tort law is to those cases that hold inde-

pendent tortfeasors jointly and severally liable for a plaintiff's injuries where neither the plaintiff nor the defendants can identify the particular tortfeasor who actually caused the plaintiff's injuries. Under these doctrines, there is potential for a 100% error in matching liability with actual responsibility for the harm (*i.e.*, a single innocent defendant can be held liable for 100% of the harm caused by another). The classic situation occurs where three defendants each negligently shoot a rifle in the plaintiff's direction, and the bullet from one rifle injures the plaintiff. Where neither the plaintiff nor the defendants know whose bullet struck the plaintiff, the defendants are jointly and severally liable for the injury. This is so even though it is clear that only one defendant's bullet caused the injury, and that the actual guilty defendant may be judgment-proof. Under the joint and several liability rules, the plaintiff may recover all of his damages from one or more defendants who are not actually guilty of causing the injury, thus creating a 100% error in matching liability with the actual cause of harm. This classic principle was first developed in *Summers* v. *Tice*, 33 Cal.2d 80, 199 P.2d 1 (1948), and is also embodied in the Restatement, Second, Torts §433B(3).

Thus, states other than Wisconsin also have acted within their traditional powers to regulate state tort law in making similar policy judgments in DES cases to allocate the burden of proof of causation-in-fact. *See, e.g., Sindell* v. *Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, *cert. denied*, 449 U.S. 912 (1980). These policy judgments are appropriate functions for the states to undertake, and do not violate the due-process rights of drug manufacturers. Petitioner's request for this Court to substitute its judgment for that of a state supreme court would in effect alter the traditional roles of the state and federal judiciary.

II.

THE COLLINS DECISION DOES NOT DEPRIVE PETITIONER OF EQUAL PROTECTION OF THE LAWS.

The Fourteenth Amendment provides that "[n]o state shall . . . deny to any person within its jurisdiction the equal protection of the laws."

A. The Collins Decision Comes Before This Court With A Presumption Of Constitutionality For Purposes Of Equal Protection Review.

As discussed above, the *Collins* decision is a rule of law affecting the economic and social welfare of the citizenry of Wisconsin. The standards for reviewing rules affecting such matters under the Equal Protection Clause are similar to the standards for review under the Due Process Clause. The major difference is that the equal-protection review tests the rationality of the "classifications" drawn by the rule of law.

This Court, in *City of New Orleans* v. *Dukes*, 427 U.S. 297 (1976), noted that unless a classification trammels fundamental personal rights or is drawn upon inherently suspect distinctions such as race, religion, or alienage, this Court's decisions presume the constitutionality of the statutory discriminations. So long as the classification challenged is rationally related to a legitimate state interest, states are accorded wide latitude in the regulation of their local economies under their police powers. Moreover, the states' rational distinctions may be made with substantially less than mathematical exactitude. 427 U.S. at 303-04.

B. The Classifications Drawn In The Collins Decision Are Rationally Related To A Legitimate State Interest.

Petitioner argues that the *Collins* rule treats it differently than defendants in other tort cases. The classification, however, is not *DES manufacturers* versus all other defendants in tort cases, as Petitioner suggests. Rather, the Wisconsin Supreme Court noted that its adaptation of the causation element in tort cases would "apply in situations which are factually similar to the DES cases." Pet. App.-18. The classification thus applies in situations where manufacturers market a product that is harmful and actually causes harm, but because of the passage of time and the fungibility (i.e., identical chemical composition and appearance) of the various brands the victim cannot pinpoint which defendant manufactured the precise item that caused the harm (here, DES pills). This is appropriate, as noted earlier, because the manufacturers are in a better position than the victim to know where and when their products were marketed, and consequently whether their brand could have been one which caused the harm.

A state has a legitimate interest in compensating its citizens for injuries caused by dangerous products. The *Collins* formulation accommodates this interest by establishing a rebuttable presumption of causation-in-fact in limited circumstances that nevertheless extend beyond DES cases. This variation on usual causation rules is made for a simple common-sense reason. The rules are different because the circumstances of a DES daughter's injuries are different than the circumstances of the injuries in most tort cases.

Ms. Collins was injured by one of the many drug manufacturers that produced the identical drug using an identi-

cal formula. She cannot pinpoint exactly which among the manufacturers actually provided the product that caused her injuries because of the product's fungibility and the fact that it did not produce discoverable damage to her until almost 20 years after its purchase and ingestion by her mother.

The Wisconsin Supreme Court was faced with the difficult choice between denying compensation to plaintiffs like Ms. Collins or adapting its common law to the unusual circumstances of their injuries. The Wisconsin Supreme Court chose the latter alternative. Because the circumstances of Ms. Collins' injuries prevented her from identifying the particular tortfeasor who actually caused her harm, the Wisconsin Supreme Court had no choice but to depart from the rules generally used in tort cases to establish the element of causation. Such departures are not uncommon to Wisconsin and other states' law. As stated earlier, the Wisconsin Supreme Court and the courts of other states, as reflected in Section 433B(3) of the Second Restatement of Torts, have made exactly the same policy judgment. The *Collins* formulation is drawn so that it creates a potential for error that is actually smaller than that in the other "unidentified defendant" cases. Because the *Collins* rule reduces the potential for error and addresses the same circumstances as other well-established causation doctrines of state tort law, an equal-protection challenge to *Collins* can, necessarily, be no more persuasive than an equal-protection challenge to the Restatement of Torts.

III.

THE STATE SUPREME COURT'S APPLICATION OF THE STATE CONSTITUTION IN THE COLLINS DECISION TO MODIFY THE STATE COMMON LAW DOES NOT INFRINGE ON PETITIONER'S FOURTEENTH AMENDMENT RIGHTS.

The Wisconsin Supreme Court is, of course, the final authority on the meaning of the Wisconsin Constitution. That court's interpretation of the state constitution to permit the rebuttable presumption established in the *Collins* decision and used in considering the state law tort question raised there, is not subject to the federal revision Petitioner would like. Rather, the Wisconsin Supreme Court's interpretation and application of its own constitution may be overturned only if the state interpretation violates federal constitutional principles, which it does not do.

IV.

THE COLLINS DECISION IS NOT INVALID UNDER THE SUPREMACY CLAUSE.

The Supremacy Clause of the United States Constitution provides that the "Constitution and the laws of the United States which shall be made in pursuance thereof; and all Treaties made or which shall be made under the authority of the United States shall be the supreme law of the land . . . ." Article VI, Clause 2. Thus, to the extent that Congress has exercised one of its powers, any inconsistent state law is prohibited. It is unclear precisely what aspects of federal policy or law Petitioner claims are frustrated or interfered with in the *Collins* decision. We will, therefore, address each of the possible Supremacy Clause

elements that have been identified as subject to analysis in this Court's treatment of similar questions.

In its decision in *Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151 (1978), this Court noted that the congressional purpose to supersede the police power of the states may manifest itself through a scheme of federal regulation which is so pervasive that it is reasonable to infer that Congress left no room for the states to supplement it; or may exist where the regulatory field is one in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject; or where the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose as the state ruling; or where a state rule actually conflicts with or stands as an obstacle to the accomplishment of goals embodied in a valid federal statute, and so is void to that extent. 435 U.S. at 158. Consideration of Petitioner's Supremacy Clause argument begins with the recognition that "the historic police powers of the state were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." 435 U.S. at 157.

A. Federal Law Has Not Occupied The Field Of Drug Regulation So As To Prevent States From Supplementing The Field.

Although the introduction of new drugs is extensively controlled by the federal government, a long line of United States Supreme Court cases has held that Congress left room for state and municipal regulations in that field. In *Corn Products Refining Co.* v. *Eddy*, 249 U.S. 427 (1919), this Court upheld a state statute that supplemented the federal Drug and Cosmetic Act. Furthermore, numerous

cases have recognized state civil remedies for personal injury, death, or property damage resulting to consumers from dangerous drugs. *See, e.g., Florida ex rel. Broward County* v. *Eli Lilly & Co.*, 329 F. Supp. 364, 365-66 (S.D. Fla. 1971), and the cases cited therein. Indeed, the legislative history of the federal Food and Drug Act indicates that the express provision for a private right of action for damages was included in an earlier version of the bill but was omitted from all later versions on the ground that it would create an unnecessary federal action duplicative of state remedies. *Florida ex rel. Broward County* v. *Eli Lilly & Co.*, 329 F. Supp. at 365 n.2, *citing* Hearings on S. 1944, before a Subcommittee of the Commerce Committee, U.S. Senate, 73d Cong., 2d Sess., pp. 10, 144, 219, 403, 431, 444 (1933). The federal scheme of drug regulation is simply not so pervasive as to justify the inference that a state may not supplement it with a rule of civil liability like that found in the *Collins* decision.

Nor does the federal scheme demonstrate a federal interest so dominant that it precludes state regulation of the same subject matter. Unlike some areas such as foreign affairs and immigration, state tort law traditionally has been viewed as within the proper scope of the states' police power. Congress could, of course, choose to federalize product liability law, as has been proposed in the Uniform Product Liability Law, S.44, 98th Cong., 1st Sess. (1983), now pending before Congress. Until such time as Congress chooses to do so, however, it is within the authority of the states to regulate their own tort law.

B. The Collins Decision Does Not Govern The Same Area As That Of The Federal Laws Governing A Drug Manufacturer, Nor Does The Collins Decision Conflict With Any Federal Statute.

A clear and manifest purpose of Congress to supersede the police power of a state may be shown where the object sought to be obtained by the federal government and by the challenged state rule reveal the same purpose. *Southern R. Co.* v. *Railroad Commission,* 236 U.S. 439, 447 (1915).

The *Collins* formulation is not an attempt to achieve the same purposes as the federal Drug and Cosmetic Act, nor does it impose the same obligations as that Act. The federal Act is concerned with the safety and efficacy of prescription drugs. The Act achieves this purpose through labeling, registration, and disclosure requirements. The Act makes no attempt to define or prescribe a drug manufacturer's liability for injuries caused by defective products. *Orthopedic Equipment* v. *Eutsler,* 276 F.2d 455, 460 (4th Cir. 1960).

In contrast, the *Collins* decision is merely a mechanism designed to equitably allocate responsibility for damage caused by a drug manufacturer's defective products. Its only purpose is to compensate innocent DES victims who cannot identify the manufacturer of the DES pills that caused them harm.

Because the federal Act does not purport to govern rules of civil liability arising from defective drugs and the *Collins* decision does not purport to govern labeling, registration, or disclosure requirements for drugs, the *Collins* rule is not preempted as attempting to govern the same area or impose the same obligations as an existing federal law. In this connection, Petitioner appears to make no claim

that the *Collins* decision is in direct conflict with any federal authority. It appears, indeed, that Petitioner could make no such claim.

Nor does Petitioner identify any purpose or objectives of Congress with which the *Collins* decision may conflict. We note, however, that the *Collins* decision *promotes* federal drug policies. The objective of the federal regulatory system is *not* to insulate manufacturers of *defective* products from liability. The purpose of the Food, Drug and Cosmetic Act, 21 U.S.C. §301, is to protect consumers, who in the circumstances of modern industrialism are largely beyond self-protection. *62 Cases of Jam* v. *United States*, 340 U.S. 593, 600 (1951). The *Collins* formulation does not impose liability on all manufacturers in the drug industry regardless of fault. It imposes liability *only* when a manufacturer has produced a defective product. It is consistent with, and promotes, federal policy.

Further, the *Collins* decision will not frustrate federal policies favoring the production and marketing of generic drugs. The decision in *Collins* does not assign liability without fault. To be responsible for damages under this rule, a drug manufacturer must produce a defective product. Contrary to Petitioner's arguments, such a rule will more likely serve to further, rather than frustrate, the Congressional objective to protect helpless consumers. Holding drug manufacturers liable for the injuries caused by their products will definitely provide incentives to produce safer drugs.

V.

THE COLLINS DECISION IS NOT A REGULATION AFFECTING INTERSTATE COMMERCE.

The Commerce Clause of the United States Constitution provides that Congress shall have the power "[t]o regulate Commerce . . . among the several States." Article I, Section 8, Clause 3. Petitioner claims that the *Collins* decision contravenes the Commerce Clause by creating an impermissible burden on interstate commerce. However, it is well established that civil remedies—which only "indirectly" relate to or affect interstate commerce—are not "regulations" for purposes of the Commerce Clause.

The constitutionality of civil remedies under the Commerce Clause has been thoroughly treated by this Court in such long-standing precedent as *Missouri, Kansas & Texas R. Co.* v. *Haber,* 169 U.S. 613 (1898), and *Sherlock* v. *Alling,* 93 U.S. 99 (1876). Where state statutes establishing rebuttable presumptions and new rights of action are challenged as impermissible burdens on interstate commerce, this Court has rejected the challenge when it concludes that the statutes do not constitute a regulation within the meaning of the Commerce Clause. Such statutes "only declare a general principle respecting the *liability* of all persons within the jurisdiction of the State *for torts* resulting in the death of parties injured. General legislation of those prescribing the liabilities or duties of citizens of this state without distinction as to pursuit or calling is not open to any valid objection because it may affect persons engaged in foreign or interstate commerce." *Sherlock,* 93 U.S. at 103 (emphasis added).

In a similar vein, the *Haber* decision states:

> "It is said that the statute of Kansas giving a right of action for damages is, in itself, a regulation of

> commerce among the States, and therefore, inconsistent with the power of Congress to regulate such commerce. But that statute is not within the meaning of the Constitution, nor in any just sense, a regulation of commerce among the States. . . . It did nothing more than declare as a *rule of civil liability* in Kansas, that anyone driving, shipping or transporting or causing to be driven, shipped or transported, into or through any county, in that state, cattle liable to impart or capable of communicating Texas, splenic or Spanish fever to domestic cattle should be responsible to any person injured thereby." 169 U.S. at 625 (emphasis added).

In light of *Haber* and *Sherlock*, the *Collins* decision cannot be considered a regulation affecting interstate commerce.[3] The *Collins* decision does not prohibit any commerce among the states. It does nothing more than make drug manufacturers responsible for damage caused by a dangerous product. It simply fashions a rule of civil liability well within the state's inherent power to protect its citizenry. Moreover, the *Collins* decision imposes no tax, proscribes no duty and in no respect interferes with any regulations providing for the manufacture and distribution of drugs. For these reasons, the rule in the *Collins* decision is not prohibited by the Commerce Clause of the federal Constitution.

Petitioner also claims that the mere lack of uniformity among state tort law, which decisions such as *Collins* may

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[3] There are four important similarities between the rule of law in the *Collins* case and the statutes involved in *Haber* and *Sherlock*:

(a) All create or allow causes of action for negligent behavior;

(b) All involve use of rebuttable presumptions;

(c) All were challenged on Commerce Clause grounds;

(d) All did not directly affect interstate commerce.

reflect, is a burden on interstate commerce. In effect, this is an attack on the customary federal-state relationship in the area of personal injury law. The fact that present negligence standards and strict liability standards vary from state-to-state does not mean interstate commerce is impermissibly burdened. Instead, the variations are a testament to the fact that those standards are generally regarded as matters left to the states. If there were *fifty* separate state standards applied in product liability cases, that would merely be due to the legitimate operation of the safeguards for local experimentation embodied in the United States Constitution. While Congress could act to preempt the field, until it does so Petitioner's Commerce Clause arguments simply ask this Court to make a judgment as to which state's personal injury law is best, and in that manner to federalize tort law. Such a judgment would be a dramatic alteration of this Court's role in the federal-state relationship, and would be unwarranted.

Because the *Collins* rule is not a regulation affecting interstate commerce, it is unnecessary to address whether the decision is rationally related to a legitimate state end, whether the regulatory burden imposed on interstate commerce is outweighed by the state's interest, or whether there is a less burdensome alternative to the remedy chosen by the Wisconsin Supreme Court. Even if these issues were relevant, the prior discussion demonstrates that the *Collins* formulation is rationally related to a legitimate state goal, and that the Wisconsin Supreme Court arrived at this decision after carefully weighing all relevant factors.

CONCLUSION

The petition for a writ of certiorari to the Supreme Court of Wisconsin should be denied.

Respectfully submitted,

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APPENDIX

APPENDIX A

EXCERPT OF ENTIRE FEDERAL CONSTITUTIONAL ARGUMENT CONTAINED IN JOINT BRIEF OF PETITIONER AND OTHER DEFENDANT DRUG COMPANIES BEFORE THE WISCONSIN SUPREME COURT

"Because no one can predict the results of such a fundamental policy change as requested by plaintiff, and [sic] such a change is an inappropriate matter for judicial determination. *See also, Judevine* v. *Benzies-Montanye Fuel & Warehouse Co.*, 222 Wis. 512, 527, 269 N.W. 295, 302 (1936), *questioned on other gds.*, 15 Wis.2d 452, 113 N.W.2d 135 (1962); *Yoeckel* v. *Samonig*, 272 Wis. 430, 434, 75 N.W. 2d 925 (1956), also refusing to engage in 'judicial legislation."[25]

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[25] In addition, to adopt alternative or market share liability would result in a denial of both substantive and procedural due process to defendants because these theories create a mandatory presumption of liability without proof that it is more likely than not that defendant's product caused plaintiff's injuries, but rather on the basis that it simply could have done so. *See, Speiser* v. *Randall*, 357 U.S. 513, 523-24 (1958); *Wolff* v. *McDonnell*, 418 U.S. 539, 557-58 (1974). The Equal Protection clause would also be violated, *see Stanley* v. *Illinois*, 405 U.S. 645, 648, 6[illegible]5 (1972), as would the Commerce Clause, *Dean Milk Co.* v. *Madison*, 340 U.S. 349 (1951), and the Supremacy Clause, *see Sola Elec. Co.* v. *Jefferson Elec. Co.*, 317 U.S. 173 (1942), by adopting a theory of liability which erects barriers to commerce, treats generic drug manufacturers differently than other defendants, and frustrates and impedes enforcement of federal law governing prescription drugs."

[Text from page 56 of Joint Brief; footnote from pages 56-57].

APPENDIX B

LAW REVIEW ARTICLES ADDRESSING THE DES CAUSATION PROBLEM

1983:

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